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Supreme Court of the United States

FERRING B.V., FERRING PHARMACEUTICALS, INC., and AVENTIS PHARMACEUTICALS, INC.,

Petitioners,

v.

MEIJER, INC., MEIJER DISTRIBUTION, INC., ROCHESTER DRUG CO-OPERATIVE, INC., and LOUISIANA WHOLESALE DRUG CO., INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The Federal Circuit has "exclusive jurisdiction" over all appeals that are based "in whole or in part" on patent issues. 28 U.S.C. § 1295(a)(1). Accordingly, courts have consistently held that a *Walker Process* claim (i.e., an antitrust claim alleging enforcement of an invalid patent that was procured through fraud) lies within the *exclusive* jurisdiction of the Federal Circuit. In this case, however, the Second Circuit held that the Federal Circuit lacks jurisdiction over a *Walker Process* claim if plaintiffs include non-patent allegations in the same count. The court reached this conclusion even though it acknowledged that the patent fraud allegations are "the linchpin" of the case and even though the non-patent allegations would *not* provide plaintiffs a basis for obtaining all the relief they seek.

The question presented is whether the Second Circuit's new jurisdictional standard conflicts with this Court's decision in *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800 (1988), and with decisions of the Federal Circuit and Seventh Circuit, holding that the Federal Circuit has exclusive jurisdiction in any patent-based case in which patent issues must be resolved in order for plaintiffs to achieve the overall success of their claim and obtain all the damages (or other relief) they seek.

PARTIES TO THE PROCEEDINGS BELOW AND RULE 29.6 STATEMENT

Petitioner Ferring B.V. is a wholly owned subsidiary of Ferring Holding SA, a Swiss company; Petitioner Ferring Pharmaceuticals, Inc. is a wholly-owned subsidiary of Ferring Holding Inc., which is a wholly-owned subsidiary of Ferring B.V.

Sanofi-Aventis is the parent corporation of Petitioner Aventis Pharmaceuticals, Inc. (formerly known as Hoechst Marion Roussel, Inc.); no other publicly held company owns 10% or more of Aventis Pharmaceuticals, Inc.

Respondents are Meijer, Inc., Meijer Distribution, Inc., Rochester Drug Co-Operative, Inc., and Louisiana Wholesale Drug Co., Inc.

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Petitioners, Ferring B.V., Ferring Pharmaceuticals, Inc. and Aventis Pharmaceuticals, Inc., respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Second Circuit in this case.

OPINIONS BELOW

The opinion of the United States Court of Appeals is reported at 585 F.3d 677. Pet. App. 1a-34a. The opinion of the district court is unreported. Pet. App. 35a-55a.

JURISDICTION

The judgment of the court of appeals was entered on October 16, 2009. Petitions for rehearing were denied on December 29, 2009. Pet. App. 56a-57a. This Court's jurisdiction is invoked pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 1295(a) of Title 28, U.S.C., provides in pertinent part:

> (a) The United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction—
>
> > (1) of an appeal from a final decision of a district court of the United States, the United States District Court for the District of the Canal Zone, the District Court of Guam, the District Court of the Virgin Islands,

> or the District Court for the Northern Mariana Islands, if the jurisdiction of that court was based, in whole or in part, on section 1338 of this title, except that a case involving a claim arising under any Act of Congress relating to copyrights, exclusive rights in mask works, or trademarks and no other claims under section 1338(a) shall be governed by sections 1291, 1292, and 1294 of this title;

Section 1338 of Title 28, U.S.C., provides in pertinent part:

> (a) The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights and trademarks. Such jurisdiction shall be exclusive of the courts of the states in patent, plant variety protection and copyright cases.

STATEMENT OF THE CASE

When Congress created the U.S. Court of Appeals for the Federal Circuit in 1982, its "central purpose" was two-fold: (i) "to reduce the widespread lack of uniformity" in appellate decisions involving patents, and (ii) to eliminate appellants' "incentive to forum-shop" among courts of appeals in an effort to locate the most hospitable tribunal to hear appeals involving patents. H.R. Rep. No. 97-312, at 23 (1981). To achieve these

goals, Congress granted *exclusive* jurisdiction to the Federal Circuit in all appeals that are based *in whole or in part* on patent law issues. 28 U.S.C. § 1295(a).

The Second Circuit ignored both the language and purpose of 28 U.S.C. § 1295(a) and adopted an erroneous jurisdictional standard that conflicts with (i) the standard set forth by this Court in *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800 (1988), and (ii) other circuit decisions in similar cases, including the Federal Circuit. In *Christianson*, this Court ruled that the Federal Circuit has *exclusive* jurisdiction over any appeal if at least one claim in the case raises substantial patent questions. As *Christianson* made clear, the fact that a plaintiff includes non-patent allegations as part of a patent-based claim is of no jurisdictional significance if the plaintiffs must address patent issues in order to obtain "the relief [they] seek" and achieve "overall" success with respect to that claim. *Id.* at 810. Here, the Second Circuit effectively re-wrote the requirements in *Christianson*. Although it recognized that patent issues are "the linchpin" of this case, Pet. App. 15a, the Second Circuit ruled that it, rather than the Federal Circuit, has jurisdiction to hear the appeal because plaintiffs included a non-patent allegation that would (if proved) entitle plaintiffs to *some* of the relief sought in their complaint. *Id.* at 15a-16a. The Second Circuit reached this astonishing conclusion even though the non-patent allegation was based on different conduct by the defendants at a different point in time, causing different injuries, and providing a basis only for damages sustained in the last few months of the multi-year period in which plaintiffs claim that defendants monopolized the market. This mischievous ruling flouts both the

letter and spirit of *Christianson*. It conflicts with decisions of the Federal Circuit and Seventh Circuit holding that the Federal Circuit has exclusive jurisdiction over cases in which patent issues must be resolved in order for a plaintiff to achieve the overall success of its claim. Finally, it thwarts Congressional intent by enabling litigants to avoid the Federal Circuit simply by artful pleading.

The Second Circuit's decision carries serious consequences for both patent policy and judicial administration. By asserting jurisdiction here, the Second Circuit was able to address an important question of patent law and policy: whether customers who *lack* standing to challenge patents directly under patent law can circumvent this prohibition by attacking the same patents under antitrust law. That issue should have been resolved by the Federal Circuit, which Congress created expressly for the purpose of resolving such patent policy issues in a uniform fashion. Instead, the Second Circuit arrogated to itself the power to rule on this important patent policy issue.

1. Factual Background

a. The Parties. Plaintiffs/respondents are drug wholesalers and retailers. They allege that defendants/petitioners (Ferring and Aventis) violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by engaging in an "overarching scheme" to monopolize the relevant market by fraudulently procuring and enforcing a patent covering the tablet form of desmopressin acetate ("the '398 patent"). Pet. App. 74a. Desmopressin acetate (which is sold under the trade name DDAVP) is a

pharmaceutical compound that is used to treat diuretic symptoms associated with diabetes insipidus (a water metabolism disorder) and to manage primary nocturnal enuresis (bed-wetting).

b. Regulatory Framework. The Federal Food, Drug, and Cosmetic Act ("FD&CA"), 21 U.S.C. §§ 301-399a, requires a company seeking to market a new drug to file a New Drug Application ("NDA") with the U.S. Food & Drug Administration ("FDA") and to obtain the agency's approval prior to marketing that drug. If an approved drug is covered by certain types of patents, the NDA holder must identify those patents to the FDA for inclusion in an FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." Pet. App. 67a.

In certain circumstances, the FD&CA permits companies to obtain approval to market the generic equivalent of a drug by filing an Abbreviated New Drug Application ("ANDA") and showing, among other things, that the generic product is bioequivalent to the approved product. *Id.* at 69a. If it seeks FDA approval to sell a generic drug before any patent listed in the Orange Book expires, a generic drug manufacturer must certify to the FDA that its generic drug will not infringe the patents listed in the Orange Book, and/or that the listed patents are invalid. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (known as a "Paragraph IV Certification"). The generic drug manufacturer also must give notice of this Paragraph IV Certification to the NDA holder and the patent owner. 21 U.S.C. § 355(j)(2)(B)(iv). If the NDA holder and/or patent

owner files a patent infringement suit within forty-five days of receiving notice of the Paragraph IV Certification, the FDA may not approve the ANDA until the shorter of thirty months from the receipt of that notice or a ruling on the merits by the district court. 21 U.S.C. § 355(j)(5)(B)(iii).

c. Underlying Patent Infringement Litigation. In July 2002, a generic drug manufacturer, Barr Laboratories, Inc. ("Barr") (who is not involved in the present proceedings), submitted an ANDA that sought FDA approval to market generic DDAVP tablets prior to the expiration of Ferring's '398 patent. Pet. App. 87a. Barr's ANDA included a Paragraph IV Certification that the '398 patent was invalid and/or unenforceable. *Id.* Ferring (the patent owner) and Aventis (the NDA holder and exclusive licensee of the patent) duly filed suit in the U.S. District Court for the Southern District of New York, Complaint, *Ferring B.V. v. Barr Labs., Inc.*, No. 02-Civ-9851 (S.D.N.Y. Dec. 13, 2002), alleging that Barr's filing of an ANDA to market a generic version of DDAVP tablets infringed the '398 patent (the "Patent Litigation"). Pet. App. 88a.

In a summary judgment opinion issued on February 7, 2005, the district court found that the '398 patent was unenforceable because of inequitable conduct before the United States Patent and Trademark Office ("PTO") — namely, Ferring failed to disclose that some of the scientific affiants who supported the patent application had prior relationships with Ferring. *Ferring B.V. v. Barr Labs., Inc.*, No. 02-Civ.-9851 (CLB), 2005 WL 437981, at *10 (S.D.N.Y. Feb. 7, 2005). The district court did *not* conclude that the '398 patent was procured by

fraud on the PTO; the court did *not* conclude that the prior relationships would have barred the issuance of the '398 patent; and the court did *not* conclude that the patent was invalid. It simply held the patent to be unenforceable. *Id.* Subsequently, in denying Barr's motion for attorney's fees, the court specifically explained that, although it had held the patent unenforceable on the grounds of inequitable conduct, it "never found conduct rising to the level of fraud." Transcript of Record at 34, *Ferring B.V. v. Barr Labs., Inc.*, No. 02-Civ.-9851 (Mar. 1, 2007).

On February 15, 2006, a sharply divided panel of the Federal Circuit affirmed the district court's ruling that the '398 patent is unenforceable due to inequitable conduct. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1194 (Fed. Cir.), *cert. denied*, 127 S. Ct. 515 (2006). Dissenting from the panel opinion, Judge Newman filed a detailed opinion concluding that Ferring's conduct did not even rise to the level of inequitable conduct, let alone the significantly higher level of intent and materiality required to establish fraud on the PTO. *Id.* at 1195-1205.[1]

1. The distinction between "inequitable conduct" (which was found in the Patent Litigation) and "fraud" (which plaintiffs in this action must prove to prevail) is an important one in antitrust cases based on patent misconduct (so-called *Walker Process* cases). *See Walker Process Equip. Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965). "A finding of inequitable conduct does not by itself suffice to support a finding of *Walker Process* fraud, because 'inequitable conduct is a broader, more inclusive concept than the common law fraud needed to support a *Walker Process* counterclaim.'" *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1346 (Fed. Cir. 2007).

d. District Court Antitrust Proceedings. Shortly after the district court issued its summary judgment ruling in the Patent Litigation, wholesale and retail DDAVP purchasers filed this suit in the same district court, asserting a single count of monopolization against Ferring and Aventis based upon the allegedly fraudulent procurement and enforcement of the '398 patent. Their complaint sought relief for an alleged "overarching" scheme, Pet. App. 74a, consisting of the following intertwined acts:

> (1) procuring U.S. Patent No. 5,407,398 (the "'398 patent"), which claims desmopressin acetate tablets, by committing fraud and/or inequitable conduct on the United States Patent and Trademark Office ("PTO"); (2) improperly listing the fraudulently obtained '398 patent in the United States Food and Drug Administration ("FDA") publication known as the Orange Book; (3) filing and prosecuting sham patent infringement litigation against competitors to forestall FDA approval of generic desmopressin acetate tablets; and (4) filing a sham citizen petition to further delay final FDA approval of generic desmopressin acetate tablets.

Id. at 59a.

After Ferring and Aventis filed motions to dismiss plaintiffs' complaint, the same district judge who presided over the underlying Patent Litigation dismissed the complaint with prejudice on two alternative grounds. *Id.* at 40a-51a. First, the court held

that plaintiffs failed to plead facts sufficient to state a claim of fraud on the PTO. *Id.* at 45a. Second, the court held that because plaintiffs lacked standing to challenge the '398 patent under patent law (since they were neither competitors of the patent-holder nor targets of patent enforcement), they also lacked standing to challenge the patent under antitrust law. *Id.* at 50a-51a.

2. The Court of Appeals Decision Below

The plaintiffs appealed to the Second Circuit. Aventis and Ferring moved to transfer the appeal to the Federal Circuit, which had heard the appeal of the underlying Patent Litigation. *See* Motion to Transfer Appeal to Federal Circuit, *In re DDAVP Direct Purchaser Antitrust Litig.*, No. 06-cv-5525 (2d Cir. Feb. 23, 2007). The Second Circuit vacated and remanded the case, holding that: (i) the Second Circuit, rather than the Federal Circuit, had jurisdiction over the appeal, (ii) purchasers have standing to bring antitrust suits based on patent fraud if the patent was "tarnished" by a prior finding of inequitable conduct, and (iii) plaintiffs adequately pled fraud. Pet. App. 16a, 25a, 33a.

The Second Circuit acknowledged that this appeal would fall within the exclusive jurisdiction of the Federal Circuit unless "there are reasons completely unrelated to the provisions and purposes of federal patent law why petitioners may or may not be entitled to the relief they seek under their monopolization claim." Pet. App. 15a-16a. The Second Circuit explained that plaintiffs characterized their claim as based on a single "anticompetitive scheme of which the '398 patent is the linchpin." *Id.* at 15a. The court also observed that the

first three of the four inter-related acts constituting this unitary scheme involved patent issues that otherwise fell within the Federal Circuit's exclusive jurisdiction. *Id.* at 11a. But the court then proceeded to dissect the alleged scheme, characterize each of the alleged acts as an independent "theory" of monopolization, and conclude that the Federal Circuit lacked jurisdiction because *one* of these four "theories" (i.e., the claim that defendants had improperly filed a citizen petition with FDA) could provide a basis for *some* (but not all) of the relief sought by plaintiffs in their complaint without raising patent issues. *Id.* at 11a-16a. It reached this decision despite the fact that the plaintiffs never contended that they could obtain all the relief they sought without adjudicating the core patent fraud claim.

Having concluded that it, rather than the Federal Circuit, had jurisdiction over the appeal, the Second Circuit proceeded to address the foundation for the dismissal — i.e., whether purchasers of a patented product (who clearly lack standing to challenge a patent directly, because they are neither competitors of the patent-holder nor targets of patent enforcement) nevertheless may be accorded standing to challenge the same patent under antitrust law. The Second Circuit then became the first court of appeals to rule that a purchaser who lacks standing to challenge a patent directly may do so indirectly by filing a suit under antitrust law rather than patent law. *Id.* at 25a.[2] The

2. The Second Circuit further held that standing might not be appropriate if the challenged patent had not yet been "tarnished" by "inequitable conduct." Pet. App. 25a. The Second Circuit also overturned the district court's alternative ruling that, as a matter of law, plaintiffs had not pled their patent fraud claims with sufficient particularity. *Id.* at 33a.

Second Circuit did so despite acknowledging that "expanding the universe of patent challengers" creates a "risk of disturbing the incentives for innovation," an issue directly at the heart of patent policy. *Id.* at 15a.

REASONS FOR GRANTING THE PETITION

I. THE DECISION BELOW ADOPTS A JURISDICTIONAL STANDARD THAT CONFLICTS WITH *CHRISTIANSON v. COLT*

A. Under *Christianson*, the Second Circuit Lacked Jurisdiction Over the Appeal Because the Relief Sought by Plaintiffs Depends Upon the Resolution of Patent Issues

The Federal Circuit has "exclusive" appellate jurisdiction over all appeals that are based, "*in whole or in part*," on substantial questions of patent law. 28 U.S.C. § 1295(a) (emphasis added). In *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800 (1988), this Court held that the Federal Circuit has exclusive jurisdiction over appeals of antitrust cases involving patent issues if *either* of two tests is met:

(i) The Federal Circuit has exclusive jurisdiction over an appeal if patent law creates the cause of action that is asserted in at least one of the claims in the case. 486 U.S. at 807-08. (This basis for jurisdiction is not at issue here, because (as in *Christianson*) plaintiffs have asserted their claims under federal antitrust law. 486 U.S. at 808-09.)

(ii) The Federal Circuit also has exclusive jurisdiction over an appeal if, with respect to at least *one* of the claims in the case, "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." *Id.* at 809. If a claim is brought under the antitrust laws, the Federal Circuit has exclusive jurisdiction over the appeal if the plaintiff needs to address substantial patent questions in order to obtain "the relief it seeks" under that claim. *Id.* at 810.

Thus, if a complaint contains more than one claim, it does not matter if most of the claims have nothing to do with patents; as long as *one* claim raises substantial patent questions, the Federal Circuit has exclusive jurisdiction over the *entire* appeal. It is not surprising then, that where plaintiffs allege that a defendant violated the antitrust laws by fraudulently obtaining and enforcing a patent (i.e., a so-called *Walker Process* claim[3]), the Federal Circuit has exclusive jurisdiction over the entire appeal, even if non-patent claims are

3. *See supra* note 1. To prove a *Walker Process* claim, the plaintiff must prove, *inter alia*, that a patent was knowingly and fraudulently (rather than inequitably) obtained, and that it is not just unenforceable but invalid. *See, e.g., Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070-71 (Fed. Cir. 1998) (finding that inequitable conduct before the PTO will not support a claim for actual or attempted monopolization); *Argus Chem. Corp. v. Fibre Glass-Evercoat Co.*, 812 F.2d 1381, 1383-84 (Fed. Cir. 1987) (same); *Brunswick Corp. v. Riegel Textile Corp.*, 752 F.2d 261, 265 (7th Cir. 1984) (holding that "for a fraud to be material in an antitrust sense the plaintiff must show that but for the fraud no patent would have been issued to anyone.").

also asserted in the complaint. *Christianson*, 486 U.S. at 808, 822-24.[4] Moreover, as this Court made clear in *Christianson*, if a claim is predicated upon alternative "theories" (i.e., both patent theories and non-patent theories), the claim is subject to the exclusive jurisdiction of the Federal Circuit *unless* the plaintiff can achieve the "overall success" of the claim (*id.* at 810) and obtain all the "relief it seeks" under that claim (*id.*) by relying on a theory that *does not raise any patent law issues*. The fact that a complaint contains non-patent allegations is of no jurisdictional significance when at least part of the relief sought by the plaintiff is dependent upon the resolution of patent questions.

Thus, the Federal Circuit, not the Second Circuit, has jurisdiction over this appeal — because plaintiffs' entitlement to the *relief they seek* necessarily depends upon resolution of disputed patent issues. *Id.* The core of plaintiffs' claim is that defendants violated the antitrust laws by fraudulently procuring and enforcing an invalid patent — i.e., a *Walker Process* claim that is unquestionably subject to Federal Circuit jurisdiction.

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4. *Accord, e.g., Tiger Team Techs., Inc. v. Synesi Group, Inc.*, No. 2009-1508, 2009 WL 3614522, at *1 (Fed. Cir. 2009); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1330 n.8 (Fed. Cir. 2008); *Jacobsen v. Katzer*, 535 F.3d 1373, 1377 (Fed. Cir. 2008); *Amini Innovation Corp. v. Anthony Cal., Inc.*, 439 F.3d 1365, 1368 (Fed. Cir. 2006); *see also Bd. of Regents, The Univ. of Tex. Sys. v. Nippon Tel. & Tel. Corp.*, 414 F.3d 1358, 1363 (Fed. Cir. 2005); *Hunter-Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1331 (Fed. Cir. 1998) ("With one claim properly in federal court, the others follow...."), *overruled on other grounds by Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999).

Plaintiffs' complaint alleged an anticompetitive "scheme" in which the '398 patent was "the linchpin," and in which three of the four inter-related acts constituting the scheme unquestionably raised issues about the '398 patent. Pet. App. 11a, 15a. Under *Christianson*, that should have ended the court's jurisdictional analysis and compelled the court to remit the appeal to the Federal Circuit, since plaintiffs clearly cannot prove the "overall" scheme and thereby obtain all the relief they seek without addressing patent issues.

In order to wrest the case from the Federal Circuit, the Second Circuit simply disregarded the unambiguous jurisdictional standard articulated by this Court in *Christianson*. Instead, it held that as long as a plaintiff could prove *a* claim under the antitrust laws (not the claim the plaintiff *actually alleged*) and obtain *some* relief (not the relief that the plaintiff *actually sought* in the complaint) without relying on patent theories, then the Federal Circuit lacks exclusive appellate jurisdiction. To reach that counter-intuitive conclusion, the Second Circuit assumed (i) that each of four acts comprising the alleged monopolization scheme constituted an independent "theory" of monopolization, and (ii) that the Federal Circuit would lack jurisdiction as long as *one* "theory" would not require resolution of patent issues. Pet. App. 9a-11a. Although the court conceded that patent law was a necessary element of the first three alleged "theories" of monopolization (i.e., fraud on the PTO, sham enforcement of a fraudulent patent, and improper listing of a fraudulent patent in the FDA Orange Book), the court ruled that the Federal Circuit lacked jurisdiction because the fourth "theory" (i.e., that defendants sought to delay approval of generic DDAVP

by filing a sham citizen petition with FDA) "could plausibly constitute *a* Sherman Act violation" — although clearly not the entire Sherman Act claim that plaintiffs had actually alleged. *Id.* at 14a (emphasis added). The court did not address the obvious fact that the citizen petition allegation involved different conduct at a different time than the alleged patent fraud, which could not possibly provide a basis for all the relief sought by plaintiffs in their complaint.

In short, the Second Circuit rewrote the jurisdictional test established by this Court in *Christianson*, which requires appellate courts to base their jurisdictional determinations on the actual claims set forth in the plaintiffs' complaint and the actual relief that is sought under those claims. 486 U.S. at 808-09. Appellate jurisdiction over patent-based cases "must be determined from what necessarily appears in the plaintiff's statement of his own claim in the bill or declaration," *id.* at 809 (quoting *Franchise Tax Board of Cal. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 10 (1983)), not predicated upon claims that plaintiffs *might* have asserted or claims that the court *might* conjure up.

Plaintiffs' complaint did not allege an antitrust claim that could be established solely by reliance upon the "theory" that defendants improperly filed a citizen petition with FDA. Rather, plaintiffs expressly alleged an "overarching scheme" to monopolize the market, caused not by any individual act but rather by "[d]efendants' conduct as a whole." Pet. App. 74a. They expressly seek a judgment declaring *all* of defendants' alleged actions (including procurement and enforcement

of the patent) to be unlawful, not just a judgment declaring the citizen petition to be unlawful. Moreover, the complaint alleges that defendants' acts injured plaintiffs during a multi-year period from February 2001 until sometime in 2005 (after generic products entered the market). *Id.* at 63a. The complaint includes a request for treble damages for *this entire period* starting in 2001, but the citizen petition was not even *filed* until 2004, *id.* at 93a, many years after the alleged monopolization scheme had commenced. Thus, the citizen petition allegations could only provide a basis for a small fraction of the damages sought in the complaint; the bulk of the damages sought by plaintiffs requires proof that the patent was invalid. If plaintiffs were to rely solely on their citizen petition "theory" and not any "theory" involving patent issues, they could obtain relief for only five months of the four and a half-year period in which they claim defendants monopolized the market.

As a result, plaintiffs could not prove their "overall" claim of monopolization, and they would not be able to obtain the "relief they seek" by relying solely on their non-patent allegations — which is what *Christianson* requires to divest the Federal Circuit of exclusive jurisdiction. 486 U.S. at 810-12. Indeed, the court below recognized that "patent-related theories are essential to the *overall* relief the plaintiffs seek" — i.e., "because the citizen petition theory covers a time period shorter than the overall allegations." Pet. App. 15a. Nevertheless, the Second Circuit ruled that because this non-patent allegation could "support[ ]" *a* Sherman Act claim (albeit not the entire claim for which relief was actually sought), *id.* at 14a, it could assert jurisdiction over this appeal despite 28 U.S.C. § 1295(a) and

notwithstanding the decisions in other circuits committing *Walker Process* cases to the exclusive jurisdiction of the Federal Cicuit. *See* note 4, *supra.*

B. The Second Circuit's Decision Paves the Way for Parties and Courts to Circumvent *Christianson* and the Federal Circuit's Jurisdiction

The Second Circuit's analysis was based on word-play rather than substance. By labeling the citizen petition allegations a "theory" rather than a "claim," the court ignored the distinction that lies at the heart of the *Christianson* analysis. The court simply assumed that antitrust allegations based on different conduct, causing different injuries, and triggering different potential remedies, were alternative "theories" rather than separate "claims."[5] If permitted to stand, the Second Circuit's rule would divest the Federal Circuit of jurisdiction over any case in which a plaintiff combines patent and non-patent allegations in a single count, instead of articulating them as separate counts. *See Christianson*, 486 U.S. at 809 n.3 ("a plaintiff may not defeat §1338 (a) jurisdiction" by its strategic

5. Tellingly, when it was not purporting to apply the jurisdictional test, the Second Circuit repeatedly referred to the patent-based allegations as "claims," not mere "theories." *See, e.g.*, Pet. App. 8a ("plaintiffs' non-*Walker Process* claims"); *id.* at 20a ("*Walker Process* claims"); *id.* at 21a ("plaintiffs have standing to bring their *Walker Process* claim"); *id.* at 30a ("the sham litigation claim has been adequately alleged"); *id.* at 31a ("plaintiffs also may proceed on their Orange Book claim"). When addressing the jurisdictional test, however, the Second Circuit characterized these same claims as "theories."

pleading choices). By accepting such artful pleading, the Second Circuit effectively eviscerated the second portion of the *Christianson* test and asserted jurisdiction over exactly the sort of case that Congress committed to the exclusive jurisdiction of the Federal Circuit.

The difference between "claims" and "theories" in the *Christianson* jurisdictional test should not be difficult for courts to discern and parties to understand. If the *entire* scope of the relief sought in a complaint (i.e., the full breadth of the judgment sought and all the damages and/or other remedies sought) can be obtained by proving *either* of two alternative factual scenarios, (1) then the scenarios are mere "theories" for proving the same claim, and (2) a regional circuit court may retain jurisdiction over an appeal even if one of the "theories" involves patent-based allegations. But where (as here) a plaintiff can obtain just a *portion* of the relief it seeks by proving a non-patent allegation (i.e., the plaintiff can obtain *all* the relief it seeks only by proving a factual scenario that *does* involve patents), the Federal Circuit has exclusive jurisdiction over the entire appeal.

Plaintiffs (and lower courts) should not be permitted to subvert the jurisdictional test in *Christianson* simply by labeling allegations as "theories" rather than "claims." The Second Circuit's erroneous jurisdictional analysis is tailor-made for manipulation, and the havoc that this decision could wreak is real. By divesting the Federal Circuit of jurisdiction over antitrust cases based on patent fraud simply because "a minor part" of the alleged misconduct involves non-patent activity, the Second Circuit has essentially invited plaintiffs to

engage in appellate forum-shopping. To avoid the Federal Circuit, all a litigant needs to do is include a minor "non-patent" allegation in a claim that is otherwise premised upon patent law issues. If a litigant thinks the Federal Circuit would provide a more hospitable forum for its case, the litigant would merely need to label its patent and non-patent allegations as separate claims in its complaint. Congress could not have envisioned that its grant of exclusive jurisdiction to the Federal Circuit would be subject to such gamesmanship.

C. The Second Circuit's Assertion of Jurisdiction Prevented the Federal Circuit from Addressing a Novel and Important Issue of Patent Law

The Second Circuit's erroneous jurisdictional standard is even more troubling because, by asserting jurisdiction in this case, the Second Circuit ensured that it — rather than the Federal Circuit — would become the first appellate court to determine whether customers who lack standing to challenge patents under patent law should be granted standing to challenge the same patents under antitrust law. In short, the Second Circuit prevented the Federal Circuit — the appellate court created to resolve patent issues in a uniform manner — from addressing one of the most important patent issues to reach the courts in years.

As the Federal Circuit has repeatedly held, and as the Second Circuit acknowledged, purchasers of a patented product (like plaintiffs in this case) lack standing to bring suit to invalidate a patent directly. "[A] patent's validity can be challenged only by a party

(1) producing or preparing to produce the patented product, and (2) being threatened or reasonably likely to be threatened with an infringement suit." Pet. App. 21a. *Accord, e.g., Cordis Corp. v. Medtronic*, 835 F.2d 859, 862 (Fed. Cir. 1987). The court below conceded that plaintiffs here did not meet the well-established test for standing to challenge a patent directly: "As purchasers of DDAVP, the plaintiffs do not satisfy these requirements and cannot directly challenge the '398 patent's validity." Pet. App. 21a. Nevertheless, the court proceeded to rule that plaintiffs who lack standing *under patent law* to challenge a patent have standing to challenge that patent *under antitrust law.*

The court's ruling is likely to have serious adverse consequences for the nation's patent system. In *Walker Process*, this Court cautioned that antitrust laws should not be expanded in a manner that might "chill the disclosure of inventions through the obtaining of a patent because of fear of the vexatious or punitive consequences of treble-damages suits." 382 U.S. at 179-80 (Harlan, J., concurring). The Second Circuit's expansive standing decision will have that chilling effect. As other circuit courts have recognized, "exposing patent activity to wider antitrust scrutiny would weaken the incentives underlying the patent system, thereby depriving consumers of beneficial products." *Data Gen. Corp. v. Grumman Sys. Support Corp.*, 36 F.3d 1147, 1186 (1st Cir. 1994).

By permitting antitrust plaintiffs to challenge patents that could not be challenged directly under patent law, the court below has exposed our nation's patent system to precisely the harm that this Court

warned against in *Walker Process*. Under the Second Circuit's ruling, any customer who wishes to challenge a patent may do so simply by bringing an antitrust claim predicated upon a patent's alleged invalidity. This ruling will undermine the value of patents and weaken the incentives to innovate that the patent system is intended to protect and enhance. The Federal Circuit — the court created by Congress to provide uniform rulings on patent law issues — should be the circuit in which this critically-important patent issue is resolved. By circumventing the jurisdictional test established by this Court in *Christianson*, the Second Circuit usurped this responsibility.

II. THE DECISION BELOW CONFLICTS WITH DECISIONS OF THE FEDERAL CIRCUIT AND THE SEVENTH CIRCUIT

By ruling that a *Walker Process* claim does not fall within the exclusive jurisdiction of the Federal Circuit, the Second Circuit placed itself in direct conflict with the Federal Circuit. In *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008), the Federal Circuit expressly stated that *Walker Process* claims are "subject to exclusive federal court jurisdiction under 28 U.S.C. § 1338(a) because the determination of fraud before the PTO necessarily involves a substantial question of patent law." *Id.* at 1330 n.8 (citation omitted). The Federal Circuit reached this unequivocal conclusion even though the *Ciprofloxacin* complaint included other allegations of monopolization that did not rest entirely on patent law. *See id.* at 1329 (describing other claims).

The Second Circuit's decision below cannot be squared with the Federal Circuit's decision to assert appellate jurisdiction in *Ciprofloxacin*. While the Second Circuit treated the *Walker Process* and citizen petition allegations in this case as alternative "theories" that *deprived* the Federal Circuit of jurisdiction, the Federal Circuit in *Ciprofloxacin* properly analyzed similar *Walker Process* and non-patent allegations and correctly treated them as separate "claims" that *vested* exclusive jurisdiction in the Federal Circuit. The only conceivable (albeit meritless) explanation for treating *Ciprofloxacin* differently from the case below is that the *Ciprofloxacin* plaintiffs chose to label their *Walker Process* allegations as a separate count from the non-patent allegations, while the plaintiffs below chose to label all their patent and non-patent allegations as the same count. But the stylistic whims of plaintiffs when they label their claims cannot alter the scope of the Federal Circuit's jurisdiction. To the contrary, this Court has repeatedly held that "courts will not permit plaintiff to use artful pleading to close off defendant's rights to a federal forum." *Federated Department Stores, Inc. v. Moitie*, 452 U.S. 394, 397 n.2 (1981). It is the obligation of the court to determine the "real nature" of the claim "regardless of plaintiff's characterization." *Id.*; *see also Christianson*, 486 U.S. at 809 n.3. Plaintiffs here claim that defendants fraudulently obtained and enforced an invalid patent. Regardless of the label affixed to this claim by plaintiffs, it constitutes a claim that is unquestionably committed to the exclusive jurisdiction of the Federal Circuit, as *Ciprofloxacin* recognizes.

The decision below also conflicts with the Seventh Circuit's decision in *U.S. Valves, Inc. v. Dray*, 190 F.3d

811 (7th Cir. 1999), and the Federal Circuit's decision in the same case, *U.S. Valves, Inc. v. Dray*, 212 F.3d 1368 (Fed. Cir. 2000). Both circuit courts agreed that the Federal Circuit had exclusive jurisdiction over an appeal where — as is the case here — plaintiff could not achieve the overall success of its claim and could recover only *some* of the damages it sought without resolving disputed patent issues.

In *U.S. Valves*, the defendant (Dray) was a patent-holder who granted U.S. Valves an exclusive license to make and sell internal piston valves covered by his patent. Dray later began selling internal piston valves and sliding ring valves. U.S. Valves filed suit against Dray, alleging that Dray's sale of both valves violated the exclusivity provision of the patent license agreement. In the district court, Dray conceded that his sale of the internal piston valves infringed the patent. This concession enabled the district court to rule that Dray had breached his patent license agreement with U.S. Valves *without* adjudicating any disputed issues regarding the patent. The district court did not address whether Dray's sale of the sliding ring valves also infringed the patent, or whether U.S. Valves would be entitled to additional damages as a result.

On appeal to the Seventh Circuit, Dray argued that the case should be transferred to the Federal Circuit, because patent law was a necessary element of that *portion* of U.S. Valves' infringement claim dealing with Dray's sale of sliding ring valves. 190 F.3d at 812-13. Relying upon *Christianson*, the Seventh Circuit examined the complaint and agreed. Even if U.S. Valves was able to prove that Dray's sale of internal piston

valves breached the license agreement without addressing disputed patent issues (because Dray had already conceded those valves were within the scope of the patent), the full amount of the damages to which U.S. Valves was entitled could not be determined without resolving whether Dray's sale of the sliding ring valves infringed the licensed patent. *Id.* at 813-15. Accordingly, the appeal was transferred to the Federal Circuit.

The Federal Circuit reviewed the jurisdictional issue *de novo* and agreed that it had exclusive jurisdiction over the case. Since "*some* of the valves that [defendant] Dray sold were of the sliding ring variety, a court must interpret the patents and then determine whether the sliding ring valve infringes these patents." 212 F.3d at 1372 (emphasis added). The fact that the plaintiff was able to establish a *portion* of its overall damages claim without raising disputed patent issues did not deprive the Federal Circuit of exclusive jurisdiction, since Dray's sale of sliding ring valves required the court to resolve a patent "case within a case" to determine if such valves were covered by the patent at issue. Consequently, the Federal Circuit concluded that "patent law is a necessary element of U.S. Valves' breach of contract action . . . [and] this court reaches the same conclusion as its sister circuit and asserts jurisdiction." *Id.*

Because U.S. Valves could not achieve the overall success of its two-part damages claim without raising disputed patent issues, both the Seventh Circuit and the Federal Circuit concluded that the Federal Circuit had exclusive jurisdiction over the case. In contrast, the Second Circuit ruled that the Federal Circuit did *not*

have exclusive jurisdiction over this case because plaintiffs could obtain *some* of the damages they sought without addressing disputed patent issues.

The jurisdictional rule followed in *U.S. Valves* is the correct one. Regardless of whether allegations are deemed a "theory" or a "claim," the Federal Circuit has exclusive jurisdiction in any patent-based case in which patent issues must be resolved in order for plaintiffs to achieve "overall success" and obtain all the damages (or other relief) they seek. Here, plaintiffs' citizen petition allegations cannot possibly provide a basis for obtaining all the relief they seek. Because the citizen petition was not even filed until the end of the alleged monopolization period, the patent fraud issues *must* be addressed if plaintiffs are to obtain damages (or other relief) for the entire period at issue in this case.

The conflict between the jurisdictional standards used by the Second Circuit and the Federal Circuit is further underscored by the recent decision of the Federal Circuit in *Davis v. Brouse McDowell, L.P.A.*, __ F.3d __, No. 2009-1395, 2010 U.S. App. LEXIS 4266 (Fed. Cir., March 2, 2010). In *Davis*, the plaintiff brought a single claim for common law malpractice against her attorney, based on the attorney's negligence in preparing and filing patent applications for her invention. Plaintiff's malpractice claim was based on two factual allegations: that her attorney (i) failed to file international patent applications under the Patent Cooperation Treaty, and (ii) committed errors in preparing her application for a U.S. patent. It was undisputed that issues of U.S. patent law were raised *only* by the second allegation. *Id.* at *9-10.

Plaintiff's argument against Federal Circuit jurisdiction was remarkably similar to the argument adopted by the Second Circuit below. She argued that she had alleged "a single claim" for malpractice supported by two "theories." Because it was undisputed that one of these "theories" did not involve U.S. patent issues, she argued that the Federal Circuit lacked jurisdiction. *Id.* The Federal Circuit, however, rejected this argument and ruled that it had exclusive jurisdiction. Even though plaintiff had combined her allegations into a single claim, the Federal Circuit ruled that the allegations were not mere "theories" for the same claim. The Court explained that plaintiff's allegation relating to the international patent applications and her allegation relating to the U.S. patent application arose out of "different sets of operative facts," and therefore were different "claims," not different "theories." *Id.* at *10. The fact that plaintiff combined these different allegations of negligence into a single claim in her complaint did not deprive the Federal Circuit of jurisdiction, because some of the allegations involved disputed U.S. patent issues.

There is no way to reconcile the jurisdictional ruling in *Davis* with the Second Circuit's ruling below. Here, plaintiffs' citizen petition claim and patent fraud claim involved different conduct, before different agencies, during different time periods, causing different alleged damages; thus, the claims unquestionably involved "different sets of operative facts." The Federal Circuit's assertion of jurisdiction in *Davis* is in direct conflict with the Second Circuit's finding that the citizen petition and the patent fraud claims are simply alternative "theories" that deprive the Federal Circuit of jurisdiction. The

Davis case confirms that there is a split among the circuits regarding the standards for determining Federal Circuit jurisdiction.

III. THE RULING BELOW RAISES IMPORTANT QUESTIONS OF FEDERAL PATENT LAW AND UNDERMINES CONGRESS' PURPOSE IN CREATING THE FEDERAL CIRCUIT

Although plaintiffs have brought their claim under federal antitrust law, this case is first and foremost a patent case. The '398 patent is "the linchpin" of plaintiffs' claim, Pet. App. 15a, and plaintiffs will need to prove the '398 patent is invalid in order to obtain the relief they seek. They will also need to prove that defendants did not have any basis for believing they would prevail on their patent infringement claims. Thus, hotly disputed issues of patent law will lie at the core of this case. This is precisely the sort of case that Congress intended the Federal Circuit to hear on appeal. *See, e.g.*, *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*,, 375 F.3d 1341, 1357 (Fed. Cir. 2004), *rev'd on other grounds*, 546 U.S. 394 (2006) (*Walker Process* claims raise "an issue *unique* to the patent law"). But under the new jurisdictional test adopted by the Second Circuit, a litigant may deprive the Federal Circuit of jurisdiction over patent-based cases like this one simply by engaging in artful pleading. All a litigant needs to do is add some non-patent allegation to its core patent fraud claim; as long as the non-patent allegation could be characterized as supporting any claim (even a much narrower claim than the one alleged in the complaint), the Federal Circuit would be divested of its exclusive jurisdiction. That outcome is contrary to the clear intent of Congress in creating the Federal Circuit.

Congress' decision to vest the Federal Circuit with exclusive jurisdiction over cases relating *in whole or in part* to patent law was motivated by a Congressional concern with lack of uniformity in the patent laws. *See* H.R. Rep. No. 97-312, at 22 (1981) ("The infrequency of Supreme Court review of patent cases leaves the present judicial system without any effective means of assuring evenhandedness nationwide in the administration of the patent laws."). A key Congressional objective in creating the Federal Circuit was "to reduce the widespread lack of uniformity and uncertainty of legal doctrine that exist in the administration of patent law." *Id.* at 23; *see also* S. Rep. No. 97-275, at 5 (1981) ("The creation of the Court of Appeals for the Federal Circuit will produce desirable uniformity in this area of the law."). Congress did not intend for the Federal Circuit to be deprived of jurisdiction of "patent issues merely couched in antitrust terms." S. Rep. No. 97-275, at 37-38. The important question of whether purchasers of patented products should be able to circumvent longstanding patent rules prohibiting them from filing patent challenges, merely by formulating those patent challenge as "antitrust" claims, is exactly the sort of patent policy issue that the Federal Circuit should resolve uniformly, rather than allowing different rules to spring up among regional circuit courts. Indeed, the Second Circuit's standing ruling cannot be reconciled with existing case law in the Federal Circuit, which has sought to harmonize patent and antitrust jurisdictional standards. *See, e.g.*, *Unitherm Food Sys.*, 375 F.3d at 1358 (applying same jurisdictional standards in patent declaratory judgment suit and antitrust suit).

Congress' decision to vest *exclusive* appellate jurisdiction of patent-related appeals in the Federal Circuit was also intended to address widespread concern with the practice of "forum shopping" by litigants looking to find friendly appellate courts in patent cases. *See* H.R. Rep. No. 97-312, at 22 ("A single court of appeals for patent cases will promote certainty where it is lacking to a significant degree and will reduce, if not eliminate, the forum shopping that now occurs."); *id.* at 23 ("Removing the incentives to forum-shop also will reduce cost to litigants."). Permitting the Second Circuit's erroneous jurisdictional decision to stand will frustrate the purpose of the Federal Circuit and facilitate the practice of forum shopping that Congress sought to eliminate when it created the Federal Circuit. The jurisdictional test adopted here by the Second Circuit will be so easy to manipulate that litigants will be able to determine in advance whether the Federal Circuit or a regional circuit court will hear their patent-based appeals.

If the decision of the Second Circuit is left standing, jurisdiction over patent-related appeals will be defined by the creativity of litigants in formatting the allegations in their complaint, and by their skills in "artful" pleading. Form will trump both substance and Congressional intent.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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March 26, 2010

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT DECIDED OCTOBER 16, 2009

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

Docket No. 06-5525-cv

In Re: DDAVP DIRECT PURCHASER ANTITRUST LITIGATION,

Meijer, Inc., Meijer Distribution, Inc., on behalf of themselves and all others similarly situated,

Plaintiffs-Appellants,

Rochester Drug Co-Operative, Inc., Louisiana Wholesale Drug Co., Inc.,

Consolidated-Plaintiffs-Appellants,

— v. —

Ferring B.V., Ferring Pharmaceuticals, Inc., Aventis Pharmaceuticals, Inc.,

Defendants-Appellees,

Appendix A

— v. —

Vista Healthplan, Inc., on behalf of itself and all others, Pennsylvania Employees Benefit Trust Fund, on behalf of itself and all others, Painters District Council No. 30 Health and Welfare Fund, Philadelphia Federation of Teachers Health and Welfare Fund,

Consolidated Plaintiffs.

Argued: Sept. 15, 2008.

Decided: Oct. 16, 2009.

Before: FEINBERG, WALKER, and LIVINGSTON, Circuit Judges.

JOHN M. WALKER, JR., Circuit Judge:

This case presents a novel question of standing that lies at the junction of antitrust and patent law. The plaintiffs, direct purchasers of desmopressin acetate tablets (sold under the name DDAVP), filed this class action in the Southern District of New York (Charles L. Brieant, *Judge*) against the defendants Ferring B.V., Ferring Pharmaceuticals (collectively, "Ferring"), and Aventis Pharmaceuticals ("Aventis"), alleging that Ferring and Aventis abused the patent system to unlawfully maintain a monopoly over DDAVP. Ferring developed, patented, and manufactures DDAVP, and Aventis holds FDA approval for DDAVP tablets as well

as a license from Ferring to market and sell the drug. The plaintiffs alleged that Ferring and Aventis inflated the price of DDAVP by suppressing generic competition for the tablets in violation of the antitrust laws. The district court dismissed the suit, concluding that the plaintiffs both lacked antitrust standing and had failed to state a claim upon which relief could be granted. This appeal followed.

BACKGROUND

The facts that follow are either undisputed or, because they are properly pled, presumed true for the purposes of this appeal at the pleading stage. *See Diaz v. Paterson*, 547 F.3d 88, 91 (2d Cir. 2008).

DDAVP is an antidiuretic prescription medication used to manage a form of diabetes, excessive urination, excessive thirst, and bed wetting. Ferring developed and manufactures DDAVP and owns U.S. Patent No. 5,047,398 (the "'398 patent"), which claims the compound in tablet form. Ferring filed its application for the '398 patent on December 17, 1985, and the Patent and Trade Office ("PTO") issued the patent on September 10, 1991. Ferring granted an exclusive license to Aventis to market and sell the patented tablets under the DDAVP name. In addition to its license from Ferring, Aventis also holds an approved New Drug Application ("NDA") from the FDA for the tablets. A manufacturer seeking to market a new drug must file an NDA to demonstrate the drug's safety and efficacy.

Appendix A

In 2002, Ferring filed a patent infringement suit against Barr Laboratories, Inc. ("Barr"), which came before the same district judge who later presided over this action. Earlier that year, Barr had filed an Abbreviated New Drug Application ("ANDA") for a generic version of the compound. An ANDA filing accelerates the approval process for a generic drug by allowing the manufacturer to rely on the safety and efficacy data provided in the NDA for the drug's branded counterpart. As part of the ANDA, Barr filed a certification (called a "paragraph IV certification") stating that the '398 patent was invalid, unenforceable, and/or would not be infringed by Barr's generic product. This filing triggered Ferring's infringement action against Barr pursuant to 35 U.S.C. § 271(e)(2).

Ferring's suit failed. On summary judgment, the district court found that the '398 patent, rather than having been infringed by Barr, was unenforceable due to inequitable conduct before the PTO by Ferring and its agents. *Ferring B.V. v. Barr Labs., Inc.*, No. 7:02-CV-9851, 2005 U.S. Dist. LEXIS 3597, 2005 WL 437981, at *10 (S.D.N.Y. Feb. 7, 2005). The Federal Circuit affirmed. *See Ferring B.V. v. Barr Labs., Inc.* ("*Ferring I*"), 437 F.3d 1181 (Fed. Cir. 2006).

The inequitable conduct that crippled the '398 patent occurred on the patent's troubled path to approval. In November 1986, PTO examiners rejected certain of the '398 patent's claims as anticipated by or obvious from U.S. Patent No. 3,497,491 (the "'491 patent"), a patent exclusively licensed to Ferring that

subsequently expired in 1987. *See id.* at 1183-84. The Board of Patent Appeals and Interferences ("BPAI") affirmed the examiners' rejection in September 1990, but on slightly different grounds: relying only on the '491 patent, the BPAI concluded that the '491 patent rendered the '398 patent "obvious" when considered "in light of" a 1973 article written by Ivan Vavra. *Id.* at 1184. In November 1990, in an effort to persuade the examiners of the '398 patent's novelty, the applicants, two Ferring employees who assigned their prospective patent rights to Ferring, submitted declarations from several scientists stating that the '491 patent and Vavra article did not suggest the '398 patent. *Id.* at 1185. It turned out, however, that four of the five declarants previously had either "been employed or had received research funds from Ferring," facts that the submissions failed to disclose to the PTO. *See id.* On the strength of these declarations, the earlier rejection notwithstanding, the PTO issued the '398 patent in September 1991. *See id.* at 1185, 1188-89. The district judge found this non-disclosure to be inequitable conduct in the Barr litigation, and determined the patent to be unenforceable. *See id.* at 1194-95.

Upon *de novo* review, the Federal Circuit held both that the undisclosed affiliations would have been material to the examiners' decision to issue the '398 patent, *see id.* at 1187-90, and that the evidence suggested that the affiants' previous relationships with Ferring were "deliberately concealed," *id.* at 1193. The Federal Circuit therefore concluded that the district court had not abused its discretion in finding inequitable conduct,

see id. at 1194-95, rendering the '398 patent unenforceable as against Barr and all other parties.

Less than two months after the Federal Circuit's February 2006 ruling, the direct purchaser plaintiffs filed the instant suit. The plaintiffs argue that the defendants' conduct, in addition to making the '398 patent unenforceable, violated the antitrust laws. They allege that defendants Ferring and Aventis "engaged in an exclusionary scheme" that included (1) "[p]rocuring the '398 patent by committing fraud and/or engaging in inequitable conduct before the PTO," (2) "[i]mproperly listing the fraudulently obtained '398 patent in the [FDA's] Orange Book," thereby enabling patent infringement claims against potential competitors, (3) prosecuting sham infringement litigation against generic competitors, and (4) "filing a sham citizen petition to further delay FDA final approval of Barr's ANDA." Compl. ¶ 144. The plaintiffs claim that the lack of competing, generic versions of DDAVP injured them by forcing them to pay monopolistic prices for the drug.

Ferring and Aventis jointly moved to dismiss the complaint on the basis that, *inter alia*, the plaintiffs lacked standing to assert their claimed antitrust violations. Aventis separately moved to dismiss the case on the ground that the plaintiffs had not sufficiently alleged misconduct against it. The district court granted both motions and dismissed the antitrust action. *See In re DDAVP Direct Purchaser Antitrust Litig.*, No. 05 Cv. 2237, 2006 U.S. Dist. LEXIS 96201, *8 (S.D.N.Y. Nov. 2, 2006).

The district court acknowledged that, while conduct in obtaining and enforcing a patent is generally protected from antitrust liability by the First Amendment, a patentee loses this immunity and can incur antitrust liability for enforcing a patent if the patent was obtained by fraud on the PTO. *See id.* at 5-6 (citing *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 173, 86 S. Ct. 347, 15 L. Ed. 2d 247 (1965)). However, the district court held that the plaintiffs failed to plead fraud on the PTO with sufficient particularity, noting that fraud requires a greater showing of culpability than the inequitable conduct that can render a patent unenforceable. *See id.* at 7-8. The district court concluded that, "[f]or this reason alone, granting the motions to dismiss is appropriate." *Id.* at 8.

However, "in the interest of completeness," the district court also considered the plaintiffs' standing. *Id.* As an initial matter, the district court noted the lack of binding precedent "with regard to the specific issue of whether purchaser plaintiffs like those in this case have standing to assert a *Walker Process* claim." *Id.* at 10-11. The district court then held that the plaintiffs lacked antitrust standing for their *Walker Process* claim because the '398 patent had not been enforced against them, and they were not competitors of Ferring or Aventis. *Id.* at 11-12 (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005); *Walgreen Co. v. Organon, Inc. (In re Remeron Antitrust Litig.)*, 335 F. Supp. 2d 522 (D.N.J. 2004)).

With little discussion, the district court also rejected the plaintiffs' non-*Walker Process* claims — the Orange Book listing, the sham infringement litigation, and the sham citizen's petition — on the basis that the defendants had not acted "in subjective bad faith." *Id.* at 13. Finally, the district court granted Aventis's separate motion to dismiss, concluding that the plaintiffs had failed to sufficiently allege that Aventis was complicit in Ferring's fraud upon the PTO. *Id.* at 14-15.

The plaintiffs now appeal the district court's decision in its entirety. They argue that the district court erred in dismissing the complaint and, in doing so, violated their due process rights. The defendants moved in this court to transfer the case on the basis that the Federal Circuit has exclusive jurisdiction over this appeal. We reserved decision on that motion.

DISCUSSION

I. Jurisdiction

We disagree that this appeal properly belongs in the Federal Circuit. The Federal Circuit has exclusive jurisdiction over appeals where the district court's jurisdiction is "based, in whole or in part, on section 1338 of [title 28]," 28 U.S.C. § 1295(a)(1), which in turn gives district courts "original jurisdiction of any civil action arising under any Act of Congress relating to patents," *id.* § 1338(a). Such jurisdiction exists if a case "arises under" patent law, such that "a well-pleaded complaint establishes either [1] that federal patent law creates the

cause of action or," as is relevant here, "[2] that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 808-09, 108 S. Ct. 2166, 100 L. Ed. 2d 811 (1988). However, "as long as there is at least one alternative theory supporting the claim that does not rely on patent law, there is no 'arising under' jurisdiction under 28 U.S.C. § 1338." *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 199 (2d Cir. 2006). In such a scenario, because "there are reasons completely unrelated to the provisions and purposes of federal patent law why petitioners may or may not be entitled to the relief they seek under their monopolization claim, the claim does not arise under federal patent law." *Id.* (quoting *Christianson*, 486 U.S. at 812).

In this case, because the plaintiffs have filed an antitrust suit, patent law does not create the cause of action. The Federal Circuit's jurisdiction over this case, if it exists, must rest upon the second part of the *Christianson* test: that "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law." 486 U.S. at 809. The plaintiffs argue that their right to relief can stand on any one of four different theories: (1) the defendants committed *Walker Process* fraud in obtaining and securing the '398 patent; (2) the defendants listed the '398 patent in the FDA's Orange Book despite knowing the patent was fraudulently procured and therefore

invalid; (3) the defendants, knowing the '398 patent was invalid, prosecuted sham patent infringement litigation against generic competitors in order to delay FDA approval of the competitors' generic DDAVP equivalent; and (4) the defendants filed a sham citizen petition, asking the FDA to require additional testing of a generic DDAVP equivalent (thus delaying its approval) despite knowing that such testing was unnecessary.

The first three of the plaintiffs' four theories plainly "depend[] on resolution of a substantial question of federal patent law," as they all turn on how the '398 patent was procured. In the absence of any fraud, actions taken by Ferring and Aventis in obtaining, maintaining, and enforcing the '398 patent would be exempt from antitrust liability. *See Walker Process*, 382 U.S. at 177 & n.5; *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981). The plaintiffs' antitrust claim, under their first three theories, requires that the '398 patent had been fraudulently procured. *See Walker Process*, 382 U.S. at 177 & n.5. In this context, fraud requires (1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, (4) but for which misrepresentation or deliberate omission the patent would not have been granted. *See C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998). Materiality, justifiable reliance, and but-for causation each implicate the issue of patentability, namely, whether the patent would have been granted in the absence of the fraudulent representations or

omissions. Because the first three theories turn on substantial questions of patent law, appellate jurisdiction would lie exclusively with the Federal Circuit if the plaintiffs' success solely depended on one or more of these theories.

The plaintiffs' fourth theory, however, does not turn on a substantial question of patent law. Under this theory, Ferring violated the antitrust laws when it filed a sham citizen petition with the FDA, requesting that the FDA require Barr to conduct extra testing to establish that its generic product was bioequivalent to DDAVP, thereby delaying approval of Barr's ANDA. Generally, under the *Noerr-Pennington* doctrine, citizen petitions are immune from antitrust liability in light of the First Amendment. *See E.R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 136, 81 S. Ct. 523, 5 L. Ed. 2d 464 (1961) ("[T]he Sherman Act does not prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or a monopoly."); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657, 670, 85 S. Ct. 1585, 14 L. Ed. 2d 626 (1965) ("Joint efforts to influence public officials do not violate the antitrust laws even though intended to eliminate competition."); *Primetime 24 Joint Venture v. Nat'l Broad. Co.*, 219 F.3d 92, 99 (2d Cir. 2000) (explaining that "concerted actions before courts and administrative agencies" are generally shielded from the Sherman Act by "the right to petition the legislature")

(citing *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510-11, 92 S. Ct. 609, 30 L. Ed. 2d 642 (1972)).

Noerr-Pennington protection is not absolute, however. When petitioning activity "ostensibly directed toward influencing governmental action[] is a . . . sham to cover what is . . . nothing more than an attempt to interfere directly with the business relationships of a competitor[, then] the application of the Sherman Act would be justified." *Noerr*, 365 U.S. at 144. This sham exception requires that the petition be "(i) 'objectively baseless,' and (ii) 'an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process — as opposed to the outcome of that process — as an anticompetitive weapon.'" *Primetime 24*, 219 F.3d at 100-01 (quoting *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.* ("*PRE*"), 508 U.S. 49, 60, 113 S. Ct. 1920, 123 L. Ed. 2d 611 (1993)).

The plaintiffs claim that the citizen petition was a sham because its sole purpose was "to delay the entry of generic competitors into the market." Compl. ¶ 105. Whether the petition was a sham is an issue independent of patent law; the substance of Ferring's citizen petition did not rest on the issuance or validity of a patent. A single lawsuit can violate antitrust law as long as it is both an objective and subjective sham. *BE&K Constr. Co. v. NLRB*, 536 U.S. 516, 526, 122 S. Ct. 2390, 153 L. Ed. 2d 499 (2002); *see also Tamoxifen*, 466 F.3d at 213 (citing *PRE*, 508 U.S. at 60). Administrative petitions,

while less susceptible than lawsuits to the sham exception, still carry the potential for antitrust liability. *See Kottle v. Nw. Kidney Ctrs.*, 146 F.3d 1056, 1062 (9th Cir. 1998) (noting that "the exact scope of the sham exception to the *Noerr-Pennington* doctrine has not always been clear in the administrative context" but finding it applicable to "a sufficiently circumscribed form of administrative authority" that is not "essentially political").

The fact that a single citizen petition may trigger the sham exception does not end our jurisdictional inquiry. Even if Ferring's citizen petition was a sham, "[p]roof of a sham merely deprives the defendant of immunity; it does not relieve the plaintiff of the obligation to establish all other elements of his claim." *PRE*, 508 U.S. at 61. Thus we must determine if any of these elements turn on a question of patent law, in which case the sham petition theory cannot be our basis for jurisdiction.

"[T]o state a claim for monopolization under Section 2 of the Sherman Act, a plaintiff must establish '(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.'" *PepsiCo, Inc. v. Coca-Cola Co.*, 315 F.3d 101, 105 (2d Cir. 2002) (per curiam) (quoting *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71, 86 S. Ct. 1698, 16 L. Ed. 2d 778 (1966)). The plaintiffs also must demonstrate an antitrust injury and damages.

See Cordes & Co. Fin. Servs., Inc. v. A.G. Edwards & Sons, Inc., 502 F.3d 91, 105 (2d Cir. 2007).

The defendants argue that, because the citizen petition was filed over a year before the '398 patent was ruled unenforceable, the plaintiffs cannot prove the necessary intent to monopolize without showing that the patent was foreseeably unenforceable — an issue that raises questions of patent law. However, the '398 patent became unenforceable almost five months before the FDA rejected the citizen petition. During that time, the defendants were free to "supplement, amend, or withdraw" the petition, 21 C.F.R. § 10.30(g), which at that point they knew to be based upon an unenforceable patent. Even if the defendants' intent when filing the petition raises questions of patent law, their intent in maintaining the petition after they lost the infringement litigation does not. And because the defendants' failure to address the citizen petition after the '398 patent became unenforceable could plausibly constitute a Sherman Act violation, the citizen petition supports a patent-independent theory of liability. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 566, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007) (suggesting that either "action or inaction" could be plausibly alleged as an antitrust violation).

The failed infringement suit also dooms the defendants' suggestion that the '398 patent's status might impact the potential for antitrust injury from the citizen's petition. If the '398 patent had been valid, Barr's ANDA might have been denied regardless of the

citizen petition. But the '398 patent had already been held unenforceable due to inequitable conduct, and the ANDA denial was plainly not inevitable (as evidenced by its ultimate approval). Thus, the plaintiffs' antitrust claim can stand on the citizen petition theory without raising questions of patent law.

Finally, the defendants argue that jurisdiction properly lies with the Federal Circuit because the plaintiffs' citizen petition theory is a minor part of the overall allegations. Indeed, the plaintiffs themselves see the petition as only a single piece of a larger anticompetitive scheme of which the '398 patent is the linchpin. But the relief sought by the plaintiffs is not tied inextricably to this larger scheme. The plaintiffs simply ask for a judgment declaring the defendants' actions to have violated the Sherman Act. *See* Compl. 37-38. The question of whether the Federal Circuit has jurisdiction "focuses on claims, not theories, and just because an element that is essential to a particular theory might be governed by federal patent law does not mean that the entire monopolization claim 'arises under' patent law." *Christianson*, 486 U.S. at 811 (internal citations omitted). The defendants stress that the plaintiffs' patent-related theories are essential to the *overall* relief the plaintiffs seek, because the citizen petition theory covers a time period shorter than the overall allegations, but this fact lacks jurisdictional significance. Focusing on claims, not theories, we have jurisdiction as long as any one of the theories can support the claim without raising substantial questions

of patent law. The citizen petition theory satisfies this requirement, and therefore we have jurisdiction over this appeal.

II. Antitrust Standing

The defendants argue that the plaintiffs lack standing to pursue this action. We review questions of standing *de novo*. *Comer v. Cisneros*, 37 F.3d 775, 787 (2d Cir. 1994). In addition to demonstrating Article III standing, an antitrust plaintiff must also establish antitrust standing. *See Paycom Billing Servs., Inc. v. Mastercard Int'l, Inc.*, 467 F.3d 283, 290 (2d Cir. 2006). We analyze antitrust standing under a two-part test: a plaintiff must show (1) antitrust injury, which is "injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful," *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489, 97 S. Ct. 690, 50 L. Ed. 2d 701 (1977), and (2) that he is a proper plaintiff in light of four "efficient enforcer" factors:

> (1) the directness or indirectness of the asserted injury; (2) the existence of an identifiable class of persons whose self-interest would normally motivate them to vindicate the public interest in antitrust enforcement; (3) the speculativeness of the alleged injury; and (4) the difficulty of identifying damages and apportioning them among direct and indirect victims so as to avoid duplicative recoveries.

Volvo N. Am. Corp. v. Men's Int'l Prof'l Tennis Council, 857 F.2d 55, 66 (2d Cir. 1988) (citing *Associated Gen. Contractors v. Cal. State Council of Carpenters ("AGC")*, 459 U.S. 519, 540-45, 103 S. Ct. 897, 74 L. Ed. 2d 723 (1983)).

In this case, the plaintiffs are purchasers of the defendants' product who allege being forced to pay supra-competitive prices as a result of the defendants' anticompetitive conduct. Such an injury plainly is "of the type the antitrust laws were intended to prevent." *Brunswick*, 429 U.S. at 489; *see also AGC*, 459 U.S. at 530 ("Congress was primarily interested in creating an effective remedy for consumers who were forced to pay excessive prices by the giant trusts and combinations that dominated certain interstate markets."). Although the defendants' conduct at issue targeted their competitors, such as Barr, the plaintiffs' claimed injury of higher prices was "inextricably intertwined" with the conduct's anti-competitive effects and thus "flow[ed] from that which makes defendants' acts unlawful." *Blue Shield of Va. v. McCready*, 457 U.S. 465, 484, 102 S. Ct. 2540, 73 L. Ed. 2d 149 (1982) (internal quotation marks omitted). Antitrust injury is therefore present.

As for the "efficient enforcer" factors that bear on whether the plaintiffs are "proper" antitrust plaintiffs, spelled out in *Volvo*, each favors granting antitrust standing. With respect to the first factor, directness of injury, even though the plaintiffs' injuries were derivative of the direct harm experienced by the defendants' competitors, harming competitors was

simply a means for the defendants to charge the plaintiffs higher prices. *See id.* at 478-79; *In re Warfarin Sodium Antitrust Litig.*, 214 F.3d 395, 400-01 (3d Cir. 2000). This factor supports the plaintiffs' standing.

As to the second factor, motivation, the defendants argue that their competitors are the parties most motivated to enforce the antitrust laws, because the competitors were most directly impacted by the alleged anticompetitive behavior. They note that we declined to find antitrust standing in *Paycom* in part because the plaintiff there was "not an entity whose self-interest would most 'motivate [it] to vindicate the public interest in antitrust enforcement.'" 467 F.3d at 294 (quoting *AGC*, 459 U.S. at 542) (alteration in original). But this argument overlooks the fact that the *Paycom* court asked if the plaintiff was *an* entity most motivated by self-interest, not *the* entity most motivated by self-interest. *See id.* The second factor simply looks for a class of persons naturally motivated to enforce the antitrust laws. "Inferiority" to other potential plaintiffs can be relevant, but it is not dispositive. *See Andrx Pharms., Inc. v. Biovail Corp., Int'l*, 256 F.3d 799, 816, 347 U.S. App. D.C. 178 (D.C. Cir. 2001). Even if the competitors might be the most motivated, the plaintiffs are also significantly motivated due to their "natural economic self-interest" in paying the lowest price possible. *See Daniel v. Am. Bd. of Emergency Med.*, 42[illegible] F.3d 408, 444 (2d Cir. 2005) (internal quotation marks omitted).

Moreover, the defendants' competitors, unlike the plaintiffs, would be seeking lost profits, not overcharges. Lost profits are the difference between the competitive price and what the competitors' costs would have been, while overcharges are the difference between the defendants' supra-competitive price and the competitive price. Denying the plaintiffs a remedy in favor of a suit by competitors would thus be "likely to leave a significant antitrust violation undetected or unremedied." *AGC*, 459 U.S. at 542; *see also Andrx Pharms.*, 256 F.3d at 817 (noting that lost profits and overcharges are distinct injuries). The second factor supports standing.

Turning to speculativeness, the third factor, the defendants argue that the plaintiffs' allegations rest upon tenuous assumptions about the beneficial effects of generic competition. The assumptions are not as speculative as the defendants suggest. That no other manufacturer would have obtained a patent on the drug is a fair assumption, we think, given that "[t]he reluctance of the PTO to issue the '398 patent was evident" in advance of the defendants' inequitable conduct. *Ferring I*, 437 F.3d at 1186. And that generic manufacturers would have decided to compete for DDAVP sales is self-evident: manufacturers sought approval for generic DDAVP when the '398 patent was still enforceable. It may be difficult to account precisely for the likely effects of generic competition, but we have little doubt that those effects can be sufficiently estimated and measured here. *See Geneva Pharms. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 499 (2d Cir.

2004) (listing literature analyzing generic drug competition). This is especially so when "[t]he most elementary conceptions of justice and public policy require that the wrongdoer shall bear the risk of the uncertainty which his own wrong has created." *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 265, 66 S. Ct. 574, 90 L. Ed. 652 (1946). Like the first two factors, the third factor supports the plaintiffs' antitrust standing.

As for the fourth factor, the potential for duplicative recovery, the difference between lost profits and overcharges is again relevant. Even assuming some overlap between lost profits and overcharges (as could occur if generic manufacturers charged more than the competitive price), the two are conceptually different measures that we think can be fairly apportioned in order to avoid duplicative recoveries. *See Andrx Pharms.*, 256 F.3d at 817. This factor also supports the plaintiffs' antitrust standing.

In sum, then, although the relative weight given to each factor is imprecise, *see, e.g.*, *Daniel*, 428 F.3d at 443, the plaintiffs would be efficient enforcers under any formulation. What complicates the standing question, however, is the centrality of the alleged *Walker Process* fraud to the plaintiffs' case. *Walker Process* claims are based on a fraudulently obtained patent, and are typically brought as counterclaims in patent infringement suits: the plaintiff claims the defendant infringed his patent, and the defendant responds that the patent was invalid as fraudulently obtained, and that the plaintiff's enforcement efforts violate *Walker*

Process. See Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1067 (Fed. Cir. 1998). If a patent is valid, a *Walker Process* claim cannot stand.

Outside of an infringement suit counterclaim, a patent's validity can be challenged only by a party (1) producing or preparing to produce the patented product, and (2) being threatened or reasonably likely to be threatened with an infringement suit. *See, e.g., Cordis Corp. v. Medtronic, Inc.*, 835 F.2d 859, 862 (Fed. Cir. 1987). As purchasers of DDAVP, the plaintiffs do not satisfy these requirements and cannot directly challenge the '398 patent's validity. As the district court noted, whether the plaintiffs have standing to bring their *Walker Process* claim, when a court has yet to find the '398 patent fraudulently obtained, is a question of first impression.

The defendants acknowledge that *Walker Process* standing might be warranted for a purchaser when a patent has already been held to have been fraudulently procured. But the defendants urge us to hold that, when dealing with a patent not yet found to be fraudulently obtained, a party has *Walker Process* standing only if that party also has standing to challenge the patent's validity. They argue that giving *Walker Process* standing to the plaintiffs, who cannot directly challenge the '398 patent's validity, could result in an avalanche of patent challenges, because direct purchasers otherwise unable to challenge a patent's validity could do so simply by dressing their patent challenge with a *Walker Process* claim. It would be relatively easy, the defendants argue,

for these purchasers to allege an antitrust injury, as patent protection inherently leads to supra-competitive prices. *See Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135, 89 S. Ct. 1562, 23 L. Ed. 2d 129 (1969) ("A patentee has the exclusive right to manufacture, use, and sell his invention."). Given that *Walker Process* fraud converts this fundamental feature of the patent system into a potential antitrust violation, the defendants contend that finding purchaser standing could significantly increase the costs of defending and enforcing patents by greatly expanding the universe of potential challenges. They insist that "[i]f the threat of treble damage liability . . . were imbedded in the minds of potential patent holders as a likely prospect . . . , the efficacy of the economic incentives afforded by our patent system might be severely diminished." *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195, 1206 (2d Cir. 1981).

Walker Process itself, of course, reflects a willingness to let antitrust liability impact the patent system. However, the defendants argue that *Walker Process* is the product of the Supreme Court's careful balancing of antitrust and patent policies, a balance which should not be upset and under which *Walker Process* plaintiffs must be independently able to first prove the patent's fraudulent procurement. Yet the language of *Walker Process* does not necessarily suggest such a limit:

> While one of [the claim's] elements is the fraudulent procurement of a patent, the action does not directly seek the patent's annulment. The gist of Walker's claim is that

> since Food Machinery obtained its patent by fraud it cannot enjoy the limited exception to the prohibitions of § 2 of the Sherman Act, but must answer under that section . . . to *those injured by any monopolistic action* taken under the fraudulent patent claim. Nor can the interest in protecting patentees from 'innumerable vexatious suits' be used to frustate the assertion of rights conferred by the antitrust laws.

382 U.S. at 176 (emphasis added). To be sure, the *Walker Process* Court also noted that allowing antitrust recovery "accord[ed]" with the "long-recognized procedures" that controlled how parties could challenge a patent's validity, 382 U.S. at 176-77, thereby suggesting that the Court may not have envisioned expanding the universe of potential patent challengers.

Nonetheless, we are reluctant to embrace the defendants' position because we are wary of creating the potential "to leave a significant antitrust violation undetected or unremedied." *AGC*, 459 U.S. at 542. As the defendants would have it, direct purchasers would be able to recover antitrust damages from a fraudulent patentee *only* after that patentee first loses on a fraudulent procurement claim. This asks too much of the generic competitors and other potential patent challengers, who may not have the strategic interest or the resources to start or win such a battle, or who may be presented with strong incentives to settle their challenge by patent holders seeking not only to

preserve their patent's enforceability, but also to avoid potential *Walker Process* liability. *See* C. Scott Hemphill, Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem, 81 N.Y.U. L. Rev. 1553, 1616 (2006) (noting how "an innovator has an especially strong incentive to pay to neutralize . . . potential competition" when a generic manufacturer first files an ANDA).

Although settlements between patent holders and generic manufacturers that delay generic entry into the market may themselves invite antitrust liability, a plaintiff must be able to show the settled litigation to have been a sham in order to succeed. *See Tamoxifen*, 466 F.3d at 208-09 ("In such a case, so long as the patent litigation is neither a sham nor otherwise baseless, the patent holder is seeking to arrive at a settlement in order to protect that to which it is presumably entitled: a lawful monopoly over the manufacture and distribution of the patented product."). A purchaser seeking to challenge the settlement by showing the underlying infringement litigation to be a sham would need to attach antitrust liability to the patent enforcement efforts — a move that would raise the same standing issues presented by this case. Thus, not only are there strong potential settlement incentives, but these settlements could be shielded from purchaser attack.

The difference between inequitable conduct and fraud also bears on the question. Inequitable conduct is a lesser showing than fraud, but is sufficient to render a patent unenforceable. A generic competitor interested

simply in selling its product may not value the higher showing of fraud enough to pursue it, especially if the competitor's antitrust damages would be minor or difficult to prove. Again, relying on generic competitors to lead the antitrust charge may ask too much of them.

On the other hand, we do not pass lightly over the defendants' objections to expanding the universe of patent challengers. The risk of disturbing the incentives for innovation dictates that we tread carefully. As a result, we decline to decide whether purchaser plaintiffs *per se* have standing to raise *Walker Process* claims. In this case, the plaintiffs are challenging an already tarnished patent. We are able to grant them antitrust standing without altering the typical limits on who can start a challenge to a patent's validity. We therefore hold only that purchaser plaintiffs have standing to raise *Walker Process* claims for patents that are already unenforceable due to inequitable conduct. The district court erred by concluding to the contrary.

III. Was the Antitrust Claim Adequately Pled

Granting standing to the plaintiffs does not resolve this appeal, because the district court also concluded that the plaintiffs had failed to state a claim. "We review the district court's dismissal of a complaint for failure to state a claim *de novo*, accepting as true all facts alleged in the complaint and drawing all inferences in favor of the plaintiff . . . ." *Faulkner v. Beer*, 463 F.3d 130, 133 (2d Cir. 2006) (internal quotation marks omitted). "[O]nly a complaint that states a plausible claim

for relief survives a motion to dismiss." *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950, 173 L. Ed. 2d 868 (2009). We believe that the plaintiffs meet this standard for their antitrust claim under each of their four theories.

Walker Process fraud, the plaintiffs' first theory, requires:

> (1) a representation of a material fact, (2) the falsity of that representation, (3) the intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent (scienter), (4) a justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, and (5) injury to the party deceived as a result of his reliance on the misrepresentation.

Nobelpharma, 141 F.3d at 1069-70. A fraudulent omission, which "can be just as reprehensible as a fraudulent misrepresentation," can be sufficient to "support a finding of *Walker Process* fraud." *Id.* at 1070.

A party "alleging fraud or mistake . . . must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). The plaintiffs argue that they have pled each element with sufficient specificity. They alleged a series of "highly material" omissions, without which "the '398 patent would not have issued." Compl. ¶ 74. The Federal Circuit agreed on the "high[ ] material[ity]" of the omissions when it found the '398

patent unenforceable. *Ferring I*, 437 F.3d at 1194. The *Ferring I* litigation also addressed the third element of intent, as the district court found "clear and convincing evidence of an intent to mislead the examiners." *Ferring B.V.*, 2005 U.S. Dist. LEXIS 3597, 2005 WL 437981, at *9. Reliance and injury, the fourth and fifth elements, are straightforward here: the PTO was justified in relying on the information the defendants provided, and injury is a "matter of course whenever the other four elements are met." *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1361 (Fed. Cir. 2004), *rev'd on other grounds*, 546 U.S. 394, 126 S. Ct. 980, 163 L. Ed. 2d 974 (2006). Thus, the plaintiffs contend the district court's dismissal on the pleadings was erroneous.

The defendants respond that the district judge's rejection of the plaintiffs' claim must be affirmed because he was also the district judge in the initial infringement litigation, in which he held the '398 patent unenforceable. The defendants argue that the judge's involvement in both cases enabled him to validly conclude that his previous findings could not support a claim of fraudulent procurement in the instant case. This is a logical non sequitur. The district judge could be correct in determining that inequitable conduct occurred and yet mistaken that such conduct did not amount to fraud. Moreover, the defendants' argument ignores the distinction between findings and pleadings. Even if the district judge was correct that the earlier record did not show fraud, the record in this case could be different following discovery.

The defendants contend that simply adding a conclusory allegation of fraud to the previous findings is inadequate to meet the plaintiffs' obligation to "allege facts that give rise to a strong inference of fraudulent intent." *Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 52 (2d Cir. 1995). We are, however, "lenient in allowing scienter issues to withstand summary judgment based on fairly tenuous inferences," because such issues are "appropriate for resolution by the trier of fact." *Press v. Chem. Inv. Servs. Corp.*, 166 F.3d 529, 538 (2d Cir. 1999). The same holds true for allowing such issues to survive motions to dismiss. The district court found "an intent to deceive" in the patent litigation. *Ferring B.V.*, 2005 U.S. Dist. LEXIS 3597, 2005 WL 437981, at *9. Granting the plaintiffs all favorable inferences as we must on a motion to dismiss, and given that the omissions at issue occurred repeatedly over a period of years, this intent is sufficient to plausibly support a finding of *Walker Process* fraud.

The defendants next argue that the plaintiffs must allege evidence of intent distinct from the omission itself. While a false or clearly misleading statement can permit an inference of deceptive intent, a misrepresentation in the form of an omission is more likely to be innocent and cannot support *Walker Process* fraud without "evidence of intent separable from the simple fact of the omission." *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1347 (Fed. Cir. 2007). The issue in the initial infringement litigation was inequitable conduct, not *Walker Process* fraud. Moreover, the district court in that litigation correctly noted that high materiality could

overcome a lesser showing of intent. *Ferring B.V.*, 2005 U.S. Dist. LEXIS 3597, 2005 WL 437981, at *9; *see Brasseler, U.S.A. I., L.P. v. Stryker Sales Corp.*., 267 F.3d 1370, 1380-81 (Fed. Cir. 2001). While such balancing is impermissible with *Walker Process* claims, we think the plaintiffs' allegations are nonetheless sufficient. *Dippin' Dots* concerned findings, not pleadings, *see* 476 F.3d at 1341-42; even if the district court's findings in the *Ferring I* litigation could not satisfy *Dippin' Dots*, the plaintiffs' pleadings could plausibly lead to additional findings that would satisfy *Dippin' Dots*, which is all that is required at this stage of the litigation.

The defendants additionally argue that the allegations of materiality are insufficient. Specifically, they contend that the plaintiffs do not dispute the '398 patent's patentability on the merits or claim that, but for the alleged fraud, no patent could have been issued to anyone. For antitrust purposes, whether a patent could be issued matters more than who would possess it; if a patent could still "have been issued to someone," its market power would still have been concentrated (properly) in one party. *Brunswick Corp. v. Riegel Textile Corp.*, 752 F.2d 261, 265 (7th Cir. 1984). As a result, *Walker Process* fraud must concern a material issue of patentability; otherwise, a patent would have issued regardless of any fraud, and potential plaintiffs would have suffered the same monopoly effects (but legitimately).

Although the plaintiffs do not address patentability directly in the complaint, the issue is implicit in their

allegations. The defendants' allegedly fraudulent affidavits were attempts to explain away prior art. The Federal Circuit found them "absolutely critical" to the defendants' overcoming the patent application's initial rejection. *Ferring I*, 437 F.3d at 1189. Whether or not these declarations, if accompanied by full disclosure, would have resulted in an enforceable patent is debatable, but we think that, at the pleading stage, the fact of non-disclosure is sufficient to properly allege materiality. Overall, then, the plaintiffs have sufficiently alleged *Walker Process* fraud to survive the defendants' motion to dismiss on the pleadings.

We likewise conclude that the sham litigation claim has been adequately alleged. In order to state a claim for sham litigation, the plaintiffs need to allege that "the litigation in question is: (i) 'objectively baseless,' and (ii) 'an attempt to interfere directly with the business relationships of a competitor through the use of the governmental process . . . as an anticompetitive weapon.'" *Primetime 24 Joint Venture v. Nat'l Broadcasting Co.*, 219 F.3d 92, 100-01 (2d Cir. 2000) (citing *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60, 113 S. Ct. 1920, 123 L. Ed. 2d 611 (1993)). Based on the same facts alleged to sustain a *Walker Process* claim, we find that in the circumstances of this case, the plaintiffs' allegations are also sufficient to make out a sham litigation claim. The defendants effectively concede as much. *See* Brief of Defendants-Appellees Ferring B.V. and Ferring Pharms. at 38 ("[A] sham litigation claim here not only requires proof that defendants defrauded

the PTO, but also that they knew their misconduct before the PTO had rendered the patent invalid. . . . [Plaintiffs'] 'sham' litigation allegation is thus substantively duplicative of their patent fraud claim. . . .").

The plaintiffs also may proceed on their Orange Book claim. The defendants all but concede that the plaintiffs would have a basis for contending the Orange Book listing was fraudulent if the '398 patent is found to have been fraudulently procured. *See id.* at 41 ("[T]he allegations regarding the Orange Book listing are — like the sham litigation claims — purely derivative of the underlying claim that the '398 patent was fraudulently procured."). Indeed, the Orange Book listing's validity flows from the patent's validity. Having determined that the *Walker Process* and sham litigation theories are still in play, we similarly conclude that the plaintiffs have adequately alleged that the defendants improperly listed the '398 patent in the FDA's Orange Book.

The final theory is the plaintiffs' citizen petition theory, which, as we have explained, stands apart from the '398 patent's validity. The district court dismissed this theory on the basis that it concerned petitioning activity protected by the First Amendment. *Id.* To reach this conclusion, the district court presumably reasoned that the plaintiffs could not plausibly show the petition to be a sham, i.e., objectively and subjectively baseless, a proposition with which we disagree. The FDA found that the citizen petition "had no convincing evidence"

and lacked "any basis" for its arguments. Compl. ¶ 115 (internal quotation marks and emphasis omitted). In the *Ferring I* litigation, the district court suggested that the petition might have been "nothing more than a hardball litigation tactic, motivated by a desire to keep out competition for as long as possible after the expiration of the patent and raise transactional costs for Barr." *Ferring B.V.*, 2005 U.S. Dist. LEXIS 3597, 2005 WL 437981, at *17. Together, these findings indicate the plaintiffs could plausibly show the citizen petition to have been a sham.

Finally, the defendants contend that the citizen petition cannot give rise to antitrust liability because it could not have impacted the FDA's decision, as the FDA ultimately rejected the petition. But this ignores the possibility that the sham petition caused a delay in generic competition, a possibility reinforced by the fact that the FDA approved the generic drug on the same day that it rejected the petition. *See* 21 C.F.R. § 10.35(d)(1) (enabling a stay of FDA action after the filing of a petition). Whether the '398 patent was valid on the date the petition was filed is immaterial to this theory's success, because the plaintiffs can plausibly show the patent to have been fraudulently procured. It may turn out at trial that this petition was not a sham, or that the FDA's approval of the generic drug was not delayed by the petition, but the possibility that the petition was a sham, and that it impacted the FDA's decision, is sufficiently plausible to defeat the motion to dismiss.

Overall, the plaintiffs have stated an antitrust claim upon which relief may be granted. Based on the pleadings, each of their four theories could plausibly succeed. The district court erred by concluding to the contrary.

IV. Can Aventis Be Kept in the Case

The district court also granted Aventis's separate motion to dismiss, concluding that the plaintiffs had not alleged fraud with sufficient particularity to satisfy Rule 9 of the Federal Rules of Civil Procedure. "Although Rule 9(b) permits knowledge to be averred generally, plaintiffs must still plead the events which they claim give rise to an inference of knowledge." *Devaney v. Chester*, 813 F.2d 566, 568 (2d Cir. 1987). In a case involving multiple defendants, plaintiffs must plead circumstances providing a factual basis for scienter for each defendant; guilt by association is impermissible. *See id.* This can consist of allegations as to who "possessed . . . knowledge" of the fraud, "when and how they obtained [that] knowledge," or even why they "should have known" of the fraud. *Id.* The district court concluded that the plaintiffs fell short of this standard. We disagree.

In the district court's view, "[t]hat Aventis would pay to license a patent which it knew to be unenforceable flies in the face of reason." *In re DDAVP*, 2006 U.S. Dist. LEXIS 96201, *25. However, we find the plaintiffs' allegations plausible, and sufficient to survive a motion to dismiss on the pleadings. At the time Aventis filed

its NDA and listed DDAVP in the Orange Book, the '398 patent's validity was already in question with the patent having been rejected twice, and the PTO having raised concerns of bias. *See Ferring I*, 437 F.3d at 1190. Yet, the plaintiffs assert that Aventis apparently made no effort to independently investigate and attest to the validity of the '398 patent. Rule 9(b) requires only the *circumstances* of fraud to be stated with particularity; knowledge itself can be alleged generally. Especially considering the long-standing relationship between Aventis and Ferring, the plaintiffs have adequately stated circumstances that give rise to a plausible inference of knowledge and liability. At this early stage, the plaintiffs need only state a plausible claim of monopolization, and they have alleged enough for their suit against Aventis to proceed.

Because the dismissal as to both Ferring and Aventis was in error, we have no cause to address the plaintiffs' claim that their due process rights were violated.

CONCLUSION

For the foregoing reasons, we VACATE the district court's dismissal of the plaintiffs' case and REMAND for further proceedings.

APPENDIX B — MEMORANDUM AND ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK DATED NOVEMBER 2, 2006

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

05 Cv. 2237 (CLB)

IN RE: DDAVP DIRECT PURCHASER ANTITRUST LITIGATION;

IN RE: DDAVP INDIRECT PURCHASE ANTITRUST LITIGATION;

THIS DOCUMENT RELATES TO: ALL ACTIONS

Memorandum and Order

Brieant, J.

Before the Court in this consolidated anti-trust class action litigation, are two motions to dismiss the Direct and Indirect Purchasers' separate class action Complaints. By joint motion filed May 1, 2006 (Doc. No. 32), Defendants Ferring B.V. and Ferring Pharmaceuticals ("Ferring") and Aventis Pharmaceuticals move to dismiss the Complaints for failure to state a claim. By motion also filed May 1, 2006 (Doc. No. 35), Defendant Aventis separately moves for the same relief. Opposition papers were filed separately by the Direct and Indirect Purchasers on June 16, 2006 and reply papers were filed July 17, 2006. Oral argument

on the motions was heard on July 21, 2006. No motion for class certification has been filed.

This case is presented as a nationwide class action, alleging violations of federal and state antitrust law, as well as unfair and deceptive trade practices. The Direct and Indirect Purchaser Plaintiffs filed their respective class action Complaints against Defendants after this Court held that a patent held by Ferring for desmopressin acetate ("DDAVP") tablets was unenforceable due to inequitable conduct before the United States Patent and Trademark Office ("PTO").[1]

The following facts are either undisputed or presumed true for purposes of these motions only. Plaintiffs' claims arise from the manufacture and marketing of DDAVP, an antidiuretic, and its generic equivalents, called desmopressin acetate. Ferring is a privately held company under the laws of the Netherlands, which developed the drug and manufactured it. Ferring is the owner and assignee of U.S. Patent No. 5,407,398 entitled "DDAVP Antidiuretic

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1. The Federal Circuit affirmed. *See Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1192 (Fed. Cir. 2006) *("Ferring I")*. A motion for rehearing or rehearing *en banc* was denied. *See Ferring B.V. v. Barr Labs., Inc.*, 2006 U.S. App. LEXIS 10765 (Fed. Cir. 2006); *see also Ferring B.V. v. Barr Labs., Inc.*, 2006 U.S. App. LEXIS 10811 (Fed. Cir. 2006). A Petition for a Writ of Certiorari was filed with the Supreme Court on September 11, 2006, an extension having been granted by Chief Justice Roberts, and certiorari was denied by the United States Supreme Court on October 30, 2006.

and Method Therefor" ("'398 patent"). The '398 patent issued on September 10, 1991. Aventis is a Delaware Corporation licensed to market and sell the invention of the '398 patent in the United States. Aventis is also the holder of an approved new drug application ("NDA"), No. 019-955, for desmopressin acetate tablets which are marketed in the United States under the product name DDAVP[R].

Plaintiffs allege that Defendants Ferring and Aventis unlawfully maintained a monopoly in the relevant market by: 1) procuring the '398 patent through fraud and/or inequitable conduct before the PTO; 2) by improperly listing the patent in the United States Food and Drug Administration's ("FDA") publication of approved "Reference Listed Drugs" called the *Orange Book*, so as to be able to assert patent infringement claims against potential competitors; 3) by instituting and prosecuting a "sham" patent infringement litigation against Barr and Teva in order to delay FDA approval of and market entry of generic DDAVP tablets; and 4) by filing a "sham" citizen petition with the FDA in an effort to further delay final FDA approval of generic desmopressin acetate tablets.

Plaintiffs allege that Defendants unreasonably restrained, suppressed and eliminated competition in the market for DDAVP and its generic equivalents, by illegally obtaining and maintaining a monopoly. The Complaints are substantially similar, but the Indirect Purchaser Plaintiffs also make claims and seek damages under the antitrust and consumer protection statutes of 23 different states. All Plaintiffs allege that as a result of Defendants' conduct, Plaintiffs and proposed Class

Members paid up to hundreds of millions of dollars more for DDAVP at "supra-competitive" prices, than they would have if competing and/or generic versions of the drug had been available. Plaintiffs allege that Defendants' purpose in proceeding with earlier patent infringement litigation (in this Court) was in order to invoke the thirty-month Hatch-Waxman stay, despite knowledge that the '398 patent had been procured by fraud and was unenforceable.

As just noted, the Indirect Purchasers' Complaint includes state claims brought under the antitrust and consumer protection statutes of the Indirect Purchaser States based on illegal monopolization of the DDAVP market. Indirect Purchasers seek disgorgement of Defendants' profits from sales of DDAVP to the extent that Defendants have been unjustly enriched.

The Direct Purchaser Plaintiffs propose the following class:

> All persons and entities in the United States that purchased DDAVP in tablet form directly from one or more of the Defendants at any time from February 18, 2001 through the date on which the anti-competitive effects of Defendants' conduct cease (the "Class Period"). Excluded from the Class are Defendants, their parents, subsidiaries and affiliates, employees, and federal government entities.

Direct Purchasers' Consolidated Amended Class Action Complaint ("Direct Purchaser Complaint") at ¶15.

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The Indirect Purchasers or Third-Party Plaintiffs propose the following class:

> All persons or entities throughout the United States and its territories who purchased and/or paid for DDAVP or generic versions of DDAVP for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries (the "Class") during the period from February 25, 2001, through the date on which the anticompetitive effects of Defendants' conduct cease ("the Class Period"). For purposes of the Class definition, persons and entities "purchased" DDAVP if they paid some or all of the purchase price.

Indirect Purchasers' Consolidated Class Action Complaint ("Indirect Purchaser Complaint") at ¶124.

Defendants Ferring and Aventis jointly move to dismiss on the bases that: 1) Plaintiffs lack standing to assert the anti-trust violations claimed; 2) that Indirect Purchaser Plaintiffs' state-law claims are preempted by federal patent law; and 3) that the state law claims suffer from other defects, meriting dismissal. Defendant Aventis also moves separately to dismiss the Complaints on the basis that Plaintiffs have not sufficiently alleged misconduct by Aventis in relation to the antitrust allegations.

Defendants' Joint Motion to Dismiss the Complaint for Failure to State a Claim

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Generally, patents can be enforced without violating the Sherman Act and patents are intended in part to keep competition off of the market for a designated period of time. Enforcing a patent to stifle competition could only be actionable if there were a wilful and knowing use of an invalid patent, which violated antitrust laws. Defendants argue that this antitrust suit is an indirect and impermissible attempt to collaterally attack the validity of the patent, while Plaintiffs respond that it is rather a garden variety antitrust claim of monopolization.

Defendants argue that Plaintiffs lack standing to assert the federal and state law claims because they are purchasers and not competitors or would-be competitors of Ferring, and because neither Ferring nor Aventis has ever threatened to enforce the patents against Plaintiff purchasers. They argue that the Court should find that the purchaser-Plaintiffs have no standing, and that "it is entirely reasonable to limit antitrust standing, . . . to only those entities directly threatened with the enforcement of a patent." *Reply at 2.*[2]

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2. The Court notes the unusual circumstance in this case, that none of the generic manufacturers, originally sued by Ferring for infringement of the '398 patent, asserted antitrust counterclaims. *See April 15, 2005 Transcript at 41-42.* "An antitrust claim premised on stripping a patentee of its immunity under the antitrust laws, is typically raised as a counterclaim by a defendant in a patent infringement. suit." *Nobelpharma Ab v. Implant Innovations*, 141 F.3d 1059, 1067 (Fed. Cir. 1998).

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It is well established that conduct in obtaining and enforcing a patent is immune from antitrust allegations, as a form of petitioning protected by the First Amendment. In *Walker Process*, the Supreme Court addressed the issue of "whether the maintenance and enforcement of a patent obtained by fraud on the Patent Office may be the basis of an action under §2 of the Sherman Act, and therefore subject to a treble damage claim by an injured party under §4 of the Clayton Act," and held that the enforcement of a patent procured by fraud on the Patent Office may be violative of §2 of the Sherman Act, provided the other elements necessary to a §2 case are present. *See Walker Process Equip., Inc., v. Food Mach. & Chem Corp.*, 382 U.S. 172, 173, 86 S. Ct. 347, 15 L. Ed. 2d 247 (1965).

The Court of Appeals for the Federal Circuit has held:

> A patentee who brings an infringement suit may be subject to antitrust liability for the anti-competitive effects of that suit if the alleged infringer (the antitrust plaintiff) proves (1) that the asserted patent was obtained through knowing and willful fraud within the meaning of *Walker Process*, or (2) that the infringement suit was "a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor," *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 81 S. Ct.

> 523, 5 L. Ed. 2d 464 (1961); *California Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 510, 92 S. Ct. 609, 30 L. Ed. 2d 642 (1972) (holding that *Noerr* "governs the approach of citizens or groups of them . . . to courts, the third branch of Government"). *See Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 62 n.6, 113 S. Ct. 1920, 123 L. Ed. 2d 611, (1993) (PRE) (declining to decide "whether and, if so, to what extent *Noerr* permits the imposition of antitrust liability for a litigant's fraud or other misrepresentations").

Nobelpharma, 141 F.3d at 1068 (some citations omitted). That Court has also set forth the following with regard to fraud:

> Applied to patent prosecution, fraud requires (1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, and (4) but for which misrepresentation or deliberate omission the patent would not have been granted. A finding of fraud can of itself render the patent unenforceable, and when accompanied by the elements of violation of the Sherman Act, as discussed in Part VI, can incur additional consequences.

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C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1364 (Fed. Cir. 1998). In *Nobelpharma*, the Court explained:

> In *Walker Process*, the Supreme Court held that in order "to strip [a patentee] of its exemption from the antitrust laws" because of its attempting to enforce its patent monopoly, an antitrust plaintiff is first required to prove that the patentee "obtained the patent by knowingly and willfully misrepresenting facts [ ] to the [PTO]." 382 U.S. at 177. The plaintiff in the patent infringement suit must also have been aware of the fraud when bringing suit.

Nobelpharma, 141 F.3d at 1068-1069.

As held in *Walker Process*, "[i]t must be remembered that we deal only with a special class of patents, i.e., those procured by intentional fraud." *Walker Process*, 382 U.S. at 172. A finding of *Walker Process* fraud "must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance, i.e., that the patent would not have issued but for the misrepresentation or omission." *Nobelpharma*, 141 F.3d at 1071.

The '398 patent now stands as unenforceable for inequitable conduct, but that misconduct has not been

shown to rise to the level of fraud, so as to lead to invalidity.

> Inequitable conduct is thus an equitable defense in a patent infringement action and serves as a shield, while a more serious finding of fraud potentially exposes a patentee to antitrust liability and thus serves as a sword. . . . [T]he remedies for inequitable conduct, while serious enough, only include unenforceability of the affected patent or patents and possible attorney fees. See 35 U.S.C. §§ 282, 285 (1994). Simply put, Walker Process fraud is a more serious offense than inequitable conduct.

Id. at 1070.

Fraud "must evidence a clear intent to deceive the examiner and thereby cause the PTO to grant an invalid patent." *Id at 1071.* In contrast, "a conclusion of inequitable conduct may be based on evidence of a lesser misrepresentation or an omission, such as omission of a reference that would merely have been considered important to the patentability of a claim by a reasonable examiner." *Id.* Fraud requires a higher threshold of both intent and materiality than does a finding of inequitable conduct and must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance. *Id. at 1070-1071.*

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The Court's findings in the prior litigation of inequitable conduct and unenforceability do not arise to the *Walker Process* requirements of fraud and invalidity. At the very least, an additional component of scienter must be shown to render actions fraudulent that might otherwise be found merely inequitable. This Court did not determine that fraud was perpetrated on the PTO, nor that but for the omissions found, the patent would not have issued. Nor could it have done so on the complete record presented in *Ferring I*.[3]

Fraud must be pleaded with particularly, under Rule 9(b) of the Federal Rules of Civil Procedure ("FRCP"). Plaintiffs did not do so, and cannot do so, consistently with the record in *Ferring I*. For this reason alone, granting the motions to dismiss is appropriate.

The Court now considers in the interest of completeness whether these plaintiffs are "proper" antitrust plaintiffs, having standing to state a *Walker Process* claim.

> The offense of monopoly under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence

3. In her dissent in *Ferring I*, Judge Newman noted that the record "does not indicate sufficient culpability to require a finding of intent to deceive." *Id* at p. 1205.

> of a superior product, business acumen, or historic accident.

United States v. Grinnell Corp., 384 U.S. 563, 570-571, 86 S. Ct. 1698, 16 L. Ed. 2d 778 (U.S. 1966).

Our Court of Appeals has held:

> To state a claim under the Sherman Act, a plaintiff, in addition to stating an antitrust violation, must allege facts sufficient to prove that it suffered antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful. The injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation. Harm to the antitrust plaintiff is sufficient to satisfy the constitutional standing requirement of injury in fact.

Joblove v. Barr Labs., Inc. (In re Tamoxifen Citrate Antitrust Litig.), 466 F.3d 187, 219, 2006 U.S. App. LEXIS 22154, *93 (2d Cir. 2006)(citations and quotations omitted).

The harm alleged by Plaintiffs in this case is in a monopoly, which kept generic versions of DDAVP off of the market and resulted in overcharges to Plaintiffs. Plaintiffs have not alleged and cannot, that they did compete or would have competed with Defendants, nor

that have they been sued or threatened with an infringement lawsuit by Defendants. Rather, they allege that they have paid higher prices for desmopressin acetate by virtue of Defendant's misconduct before the PTO and subsequent actions, which prevented the lower prices, which would have ensued from generic competition.

In *Associated General,* the Supreme Court discussed the standards for establishing standing to bring a Section 2 Sherman Act claim under Section 4 of the Clayton Act. In regard to "antitrust standing," it stated:

> The label "antitrust standing" has traditionally been applied to some of the elements of this inquiry. As commentators have observed, the focus of the doctrine of "antitrust standing" is somewhat different from that of standing as a constitutional doctrine. Harm to the antitrust plaintiff is sufficient to satisfy the constitutional standing requirement of injury in fact, but the court must make a further determination whether the plaintiff is a proper party to bring a private antitrust action.

Associated General Contractors v. Cal. State Council of Carpenters, 459 U.S. 519, 535 n.31, 103 S. Ct. 897, 74

L. Ed. 2d 723 (U.S. 1983)(citations omitted). In a subsequent case, the Supreme Court noted:

> A showing of antitrust injury is necessary, but not always sufficient, to establish standing under § 4, because a party may have suffered antitrust injury but may not be a proper plaintiff under § 4 for other reasons. Thus, in *Associated General Contractors* we considered other factors in addition to antitrust injury to determine whether the petitioner was a proper plaintiff under § 4.

Cargill, Inc. v. Monfort of Colorado, Inc., 479 U.S. 104, 110, 107 S. Ct. 484, 93 L. Ed. 2d 427 (U.S. 1986)(citations omitted). Our Court of Appeals summarized the factors of *Associated General as:*

> (1) the causal connection between the alleged antitrust violation and the harm to the plaintiff; (2) the existence of an improper motive; (3) whether the injury was of a type that Congress sought to redress with the antitrust laws; (4) the directness of the connection between the injury and alleged restraint in the relevant market; (5) the speculative nature of the damages; and (6) the risk of duplicative recoveries or complex apportionment of damages.

Balaklaw v. Lovell, 14 F.3d 793, 798 (2d Cir. 1994). The Court explained:

> Over time, courts have developed a two-pronged analysis to determine whether a

> plaintiff has antitrust standing. As a necessary first step, courts must determine whether the plaintiff suffered an antitrust injury. If the answer to that question is yes, they must then determine whether any of the other factors, largely relating to the directness and identifiability of the plaintiff's injury, prevent the plaintiff from being an efficient enforcer of the antitrust laws.

Id.

Although several district courts have addressed the question, there is no precedent binding upon this Court with regard to the specific issue of whether purchaser plaintiffs like those in this case have standing to assert a *Walker Process* claim. Plaintiffs rely on the holding of *Walgreen Co. v. Organon, Inc. (In re Remeron Antitrust Litig.) ("Remeron")*, 335 F. Supp. 2d 522 (D.N.J. 2004) (Hochbert, J.), in which the United States District Court for the District of New Jersey was faced with a case similar to the case at bar. Direct purchasers of a drug sued the manufacturer under the Sherman and Clayton Acts, claiming that fraud was perpetrated on the PTO by the manufacturer, which then monopolized the market for that drug. The *Remeron* Court concluded that a plaintiff does not have standing to state a *Walker Process* claim unless the defendant had sought to

enforce the patent against that plaintiff, or if the plaintiff had a reasonable basis for fearing such an attempted enforcement. *See Id.* at 529. The Court reasoned:

> Plaintiffs, as direct purchasers, neither produced mirtazapine nor would have done so; moreover, Plaintiffs were not party to the initial patent infringement suits. Plaintiffs may not now claim standing to bring a *Walker Process* claim by donning the cloak of a Clayton Act monopolization claim.

Id.

To the same effect, *see In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 363 F. Supp. 2d 514 (E.D.N.Y. 2005)(Trager, J.) *("Cipro")*, in which drug manufacturers' agreements settling patent infringement litigation were alleged to prevent competition for an antibiotic in violation of antitrust laws. It was held that non-infringing consumers of patented products have no cause of action to invalidate a patent, and *Walker Process* claims were preempted because they arise out of, and rest on patent law. *See Contra: Molecular Diagnostics Labs. v. Hoffmann-La Roche, Inc.*, 402 F. Supp. 2d 276, 280 (D.D.C. 2005) (Kennedy, J.), holding that customer plaintiffs have standing to litigate a *Walker Process* claim.

This Court concludes that the Courts in *Ciproflaxen* and *Remeron* have the better side of the argument.

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Plaintiffs in *Walker Process* were competitors, and not purchasers. *See Indium Corp. of America v. Semi-Alloys, Inc.*, 566 F. Supp. 1344 (N.D.N.Y. 1983) *(Walker Process* claim dismissed for failure to adequately allege any set of facts that would amount to enforcement, attempted enforcement, or threatened enforcement of defendant's patents vis-a-vis the plaintiff). As herein earlier noted and as noted by Judge McCurn in *Indium Corp.*, the Supreme Court stated explicitly in *Walker Process:* "We have concluded that the *enforcement* of a patent procured by fraud on the Patent Office may be violative of § 2 of the Sherman Act provided the other elements necessary to a § 2 case are present." *Indium Corp.*, 566 F.Supp. at 1353 (emphasis added), *citing Walker Process.*, 382 U.S. at 174.

In this case, there has been no enforcement of the patent against the customer Plaintiffs. For want of antitrust standing, as an alternative ground, the motions shall be granted.

Plaintiffs' Sham Litigation Claims

Plaintiffs argue, and Defendants deny that even if the Court should find that they lack standing to pursue *Walker Process* claims, they may nonetheless pursue a "sham litigation" claim. Plaintiffs argue that Defendants conducted sham litigation by the filing of the original infringement action against Barr Laboratories, *(Ferring I)* by listing the patent in the Orange Book of patents, and by the filing of a citizen's petition, asking that the FDA require Barr to submit additional tests of

bio-equivalence, which Plaintiffs argue was done for delay.

"Under *Professional Real Estate Investors v. Columbia Pictures Indus.*, 508 U.S. 49, 113 S. Ct. 1920, 123 L. Ed. 2d 611 (1993)], a sham suit must be both subjectively brought in bad faith and based on a theory of either infringement or validity that is objectively baseless. Accordingly, if a suit is not objectively baseless, an antitrust defendant's subjective motivation is immaterial." *Nobelpharma*, 141 F.3d at 1072. "In contrast with a *Walker Process* claim, a patentee's activities in procuring the patent are not necessarily at issue." *Id.*

Clearly Aventis had the right to bring suit, since it was not privy to the inequitable conduct. The bringing of the suit by Ferring and Aventis was not in subjective bad faith, but rather a standard response to Hatch-Waxman. Every losing litigant in the federal courts does not become a sham litigant merely by losing their case.

The same is true of the citizen petition, which is First Amendment protected activity even though delay of Barr's access to the market was foreseeable.

These claims are also dismissed.

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Aventis' Motion to Dismiss the Complaints

Aventis also moves separately (Doc. No. 35) to dismiss the Complaints, arguing that Plaintiffs have not adequately alleged any knowing participation by Aventis in the alleged fraud on the PTO and other activities. Rule 9 of the FRCP requires that: "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally." *FRCP Rule 9(b).* On a motion to dismiss for failure to plead fraud with sufficient particularity, Plaintiffs are bound by the standards of Rule 9(b), but are entitled to reasonable inferences from the facts alleged.

As earlier mentioned, Aventis is the exclusive licensee of the patent for the sale of DDAVP tablets in the United States. Plaintiffs alleged that for over thirty years, Aventis has had a "close working relationship with Ferring," and note Ferring's description of its "key commercial partnership" with Aventis. *Direct Purchaser Complaint at* ¶ 42. They argue that in the process of applying for a New Drug Application from the FDA (held by Aventis, and not Ferring), between 1989 and 1991, Aventis had to make a certification of whether there was a patent that claims the product, or a patent on which a reasonable patent infringement suit could be brought. Plaintiffs contend that between 1989 and 1991, while Ferring was submitting declarations with omissions, that Aventis had to be aware of those declarations and that Aventis had to have knowledge

of the status of the patent because the NDA would had to have been amended once the patent was granted. No such *res ipsa* is apparent to this Court. Plaintiffs also contend that Aventis had performed its own study, and therefore "must have known" that the Citizen's Petition filed by Ferring requesting the FDA to require further bioequivalence testing was baseless. This does not, in logic follow, nor is there reason to believe that having made internal studies of its own, a citizen is blocked from petitioning for studies by the FDA.

> To survive a motion to dismiss, a plaintiff bringing suit under section 1 of the Sherman Act need not allege facts that exclude the possibility that the behavior of which complaint is made is legal. *See Twombly*, 425 F.3d at 111 ("[S]hort of the extremes of 'bare bones' and 'implausibility,' a complaint in an antitrust case need only contain the 'short and plain statement of the claim showing that the pleader is entitled to relief that Rule 8(a) requires."). However, bald assertions and conclusions of law are not adequate [to state a claim] and a complaint consisting only of naked assertions, and setting forth no facts upon which a court could find a violation of the [law], fails to state a claim under Rule 12(b)(6).

In re Tamoxifen Citrate Antitrust Litig., supra, 466 F.3d at 200-201, 2006 U.S. App. LEXIS 22154 at *38-39 (some citations and quotations omitted).

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Plaintiffs have failed to allege and plead sufficient facts indicating that Aventis participated in the prosecution of the '398 Patent, or that Aventis knew or subsequently learned of Ferring's inequitable conduct to obtain the '398 Patent. That Aventis would pay to license a patent which it knew to be unenforceable flies in the face of reason. That Aventis agreed with Ferring to participate in a scheme to exploit an unenforceable patent or that Aventis shared Ferring's allegedly anti-competitive intent also makes no sense. The pleadings against Aventis are threadbare, and as understandably argued by Aventis, implicate the traditional concerns that pleadings must provide a defendant with notice of a plaintiff's claim sufficient to answer and defend and of avoiding harassment and harm to a defendant's good will. Plaintiffs have failed to meet their burden of alleging sufficiently that Aventis had knowledge of an alleged fraud upon the PTO by Ferring.

Conclusions

The motions are granted. All claims pleaded under federal law are dismissed. The claims arising under state law are dismissed without prejudice. The Clerk shall file a final judgment.

SO ORDERED.

Dated: White Plains, New York
November 2, 2006

s/ Charles Brieant
Charles L. Brieant, U.S.D.J.

APPENDIX C — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT DENYING PETITION FOR REHEARING FILED DECEMBER 29, 2009

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

06-5525-cv

In Re: DDAVP DIRECT PURCHASER ANTITRUST LITIGATION

MEIJER, INC., MEIJER DISTRIBUTION, INC., on behalf of themselves and all others similarly situated,

Plaintiffs-Appellants,

ROCHESTER DRUG CO-OPERATIVE, INC., LOUISIANA WHOLESALE DRUG CO., INC.,

Consolidated Plaintiffs-Appellants.

— v. —

FERRING B.V., FERRING PHARMACEUTICALS, INC., AVENTIS PHARMACEUTICALS, INC.,

Defendants-Appellees.

Appendix C

— v. —

VISTA HEALTHPLAN, INC., on behalf of itself and all others, PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND, on behalf of itself and all others, PAINTERS DISTRICT COUNCIL NO. 30 HEALTH AND WELFARE FUND, PHILADELPHIA FEDERATION OF TEACHERS HEALTH AND WELFARE FUND,

Consolidated Plaintiffs.

Ferring B.V., and Ferring Pharmaceuticals having filed a petition for panel rehearing, or, in the alternative, for rehearing *en banc*, and the panel that determined the appeal having considered the request for panel rehearing, and the active members of the Court having considered the request for rehearing *en banc*.

IT IS HEREBY ORDERED that the petition is denied.

For the Court
Catherine O'Hagan Wolfe, Clerk

By: s/ Frank Perez
Frank Perez, Deputy Clerk

APPENDIX D — CONSOLIDATED AMENDED CLASS ACTION COMPLAINT DATED MARCH 31, 2006

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

05 Civ. 2237 (CLB)

IN RE: DDAVP DIRECT PURCHASER ANTITRUST LITIGATION

This Document Relates To: All Actions

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT

Plaintiffs Meijer, Inc., Meijer Distribution, Inc., Rochester Drug Co-operative, Inc., and Louisiana Wholesale Drug Company, Inc. bring this action on behalf of themselves and all others similarly situated against Defendants Ferring B.V., Ferring Pharmaceuticals, Inc., (collectively, "Ferring") and Aventis Pharmaceuticals, Inc. ("Aventis") (collectively, "Defendants"), to recover threefold damages, the costs of suit and reasonable attorneys' fees for injuries sustained by Plaintiffs resulting from Defendants' violations of Section 2 of the Sherman Act, 15 U.S.C. § 2. Plaintiffs make the following allegations based upon personal knowledge as to those matters relating to themselves and upon information and belief as to all other matters.

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NATURE OF THE ACTION

1. This case arises from Defendants' unlawful scheme to maintain illegally their monopoly in the United States market for desmopressin acetate tablets. Defendants market desmopressin acetate tablets under the brand name DDAVP.

2. DDAVP is approved (1) as an anti-diuretic replacement therapy in the management of central diabetes insipidus and for the management of temporary polyuria (excessive urination) and polydipsia (excessive thirst) following head trauma or surgery in the pituitary region, and (2) for the management of primary nocturnal enuresis (bed wetting), when used either alone or an adjunct to behavioral, conditional, or other non-pharmacologic intervention. Desmopressin is also available in the form of intranasal sprays and injections.

3. As alleged more fully below, Defendants engaged in an exclusionary scheme to prevent and delay generic entry and to protect their monopoly in desmopressin acetate tablets. This scheme involved, *inter alia:* (1) procuring U.S. Patent No. 5,407,398 (the " '398 patent"), which claims desmopressin acetate tablets, by committing fraud and/or inequitable conduct on the United States Patent and Trademark Office ("PTO"); (2) improperly listing the fraudulently obtained '398 patent in the United States Food and Drug Administration ("FDA") publication known as the Orange Book; (3) filing and prosecuting sham patent infringement litigation against competitors to forestall

FDA approval of generic desmopressin acetate tablets; and (4) filing a sham citizen petition to further delay final FDA approval of generic desmopressin acetate tablets.

4. Absent Defendants' exclusionary scheme, less expensive generic versions of desmopressin acetate tablets would have been available in the market much earlier. Through their unlawful conduct, Defendants illegally deprived Plaintiffs (and the other direct purchasers who comprise the Class alleged herein) of access to substantially lower-priced generic versions of desmopressin acetate tablets, thereby causing Plaintiffs and other members of the Class to pay supra-competitive prices for DDAVP and its generic equivalents.

5. As a result of Defendants' illegal acts, Defendants have (1) unreasonably restrained, suppressed, and eliminated competition in the market for desmopressin acetate tablets; (2) illegally maintained monopoly power; (3) fixed, raised, maintained, and/or stabilized the price of desmopressin acetate tablets at supra-competitive levels; and (4) overcharged Plaintiffs and other members of the Class by hundreds of millions of dollars.

JURISDICTION AND VENUE

6. This action is brought under Section 4 of the Clayton Act, 15 U.S.C. § 15, to recover treble damages and the costs of suit, including reasonable attorneys' fees, for injuries sustained by Plaintiffs and members of the Class as a result of Defendants' violations of

Section 2 of the Sherman Act, 15 U.S.C. § 2, as alleged herein.

7. This Court has jurisdiction over the subject matter of this civil action pursuant to 28 U.S.C. §§ 1331 and 1337, and 15 U.S.C. § 15.

8. Venue is proper in this Court under 28 U.S.C. § 1391 and 15 U.S.C. § 22 because (1) Defendants transact business, committed an illegal or tortious act, and/or are found within this district; and (2) a substantial portion of the affected trade and commerce described below has been carried out in this district.

PARTIES

9. Plaintiffs Meijer, Inc. and Meijer Distribution, Inc. (collectively, "Meijer") are corporations organized and existing under the laws of the State of Michigan, with their principal place of business at 2929 Walker Avenue, NW, Grand Rapids, Michigan 49544. Meijer is the assignee of the claims of the Frank W. Kerr Co., which purchased DDAVP tablets directly from one or more of the Defendants during the Class Period, defined below.

10. Plaintiff Louisiana Wholesale Drug Company, Inc. ("Louisiana Wholesale") is a corporation organized and existing under the laws of the State of Louisiana and is located at 2085 I-49 South Service Road, Sunset, Louisiana 70584. Louisiana Wholesale purchased DDAVP tablets directly from one or more of the Defendants during the Class Period, defined below.

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11. Plaintiff Rochester Drug Co-operative, Inc. ("RDC") is a drug wholesale cooperative located at 50 Jet View Drive, Rochester, New York 14624. RDC purchased DDAVP tablets directly from one or more of the Defendants during the Class Period, defined below.

12. Defendant Ferring B.V. is a privately-held company organized and existing under the laws of The Netherlands, with its principal place of business at Postbus 184, Hoofddorp NL-2130 AD, Netherlands.

13. Defendant Ferring Pharmaceuticals, Inc. (hereinafter referred to collectively with Ferring B.V. as "Ferring") is a New York corporation with its principal place of business at 400 Rella Boulevard, Suite 300, Suffern, New York. Ferring Pharmaceuticals, Inc. is a subsidiary of Defendant Ferring B.V. Ferring is the owner and assignee of the '398 patent.

14. Defendant Aventis Pharmaceuticals, Inc. ("Aventis") is a Delaware corporation with its principal place of business at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807. Aventis is the holder of an approved New Drug Application, No. 019-955, for desmopressin acetate tablets, which are marketed in the United States under the brand name DDAVP.

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CLASS ACTION

15. Plaintiffs bring this action under Rule 23 of the Federal Rules of Civil Procedure on behalf of themselves and the following class (the "Class"):

> All persons and entities in the United States that purchased DDAVP in tablet form directly from one or more of the Defendants at any time from February 18, 2001 through the date on which the anticompetitive effects of Defendants' conduct cease (the "Class Period"). Excluded from the Class are Defendants, their parents, subsidiaries and affiliates, employees, and federal government entities.

16. The Class is so numerous that joinder of all members is impracticable. Plaintiffs believe that the Class numbers one hundred or more. Further, the Class is readily identifiable from information and records in the possession, custody, or control of Defendants.

17. There are questions of law and fact common to the Class, including:

a. whether Defendants unlawfully maintained monopoly power by delaying generic entry;

b. whether market power in a relevant market is necessary to show a violation;

c. whether direct proof of Defendants' monopoly power is available, and if available, whether it is sufficient to prove Defendants' monopoly power without the need to also define a relevant market;

d. whether Defendants committed fraud and/or inequitable conduct on the PTO;

e. whether, but for Defendants' fraud, the '398 patent would not have issued;

f. whether the activities of Defendants as alleged herein have substantially affected interstate commerce;

g. whether Defendants' citizen petition was a sham and whether it caused common harm; and

h. whether, and to what extent, Defendants' conduct caused antitrust injury to the business or property of Plaintiffs and the members of the Class, and if so, the appropriate measure of damages.

These and other questions of law and fact are common to the members of the Class and predominate over any questions affecting only individual members.

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18. Plaintiffs' claims are typical of the claims of the Class because all Class members, including Plaintiffs, sustained antitrust injury in the same way as a result of Defendants' unlawful conduct, and the claims of each Class member arise out of the same nucleus of operative facts and are based on the same legal theories.

19. Plaintiffs will fairly and adequately represent and protect the interests of the Class. Plaintiffs have retained counsel who are experienced in class action and antitrust litigation, and Plaintiffs have no interest in this litigation that is adverse to, or in conflict with, the interests of the other members of the Class.

20. A class action is superior to other available methods for the fair and efficient adjudication of the controversy because such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action. Plaintiffs know of no difficulty that will be encountered in the management of the claims advanced by the Class that would preclude class certification.

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BACKGROUND

The Regulatory System Governing Pharmaceuticals in the United States

21. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, codified at 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e) (2005), establishes procedures for obtaining approval to market pharmaceutical products in the United States.

22. A manufacturer seeking to market a new drug must file with the FDA a New Drug Application (NDA), demonstrating the safety and efficacy of its product. 21 U.S.C. § 355(b) (2005).

23. New drugs that are approved for sale in the United States by the FDA may be covered by one or more patents, which provide the patent owner with the right to seek to exclude others from making, using, and/or selling (depending on the scope of the patent) the new drug in the United States for the duration of the patents, plus any extension of the original patent period granted pursuant to the Hatch-Waxman Act described below.

24. Pursuant to 21 U.S.C. § 355(b), the applicant must list in the NDA any patents that claim the drug

for which FDA approval is being sought, or that claim a method of using the drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug.

25. The FDA maintains a list of approved "Reference Listed Drugs" in a publication entitled, "Approved Drug Products with Therapeutic Equivalence Evaluations," which is commonly known as the "Orange Book." Once the FDA approves the NDA, the manufacturer may market the new branded drug, and the branded drug may be listed in the Orange Book, along with any patent that, according to the manufacturer, (1) claims either the approved drug or, in the case of a method-of-use patent, claims the approved use of the approved drug, and (2) with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. 21 U.S.C. § 355(j)(7)(A)(iii).

26. Despite FDA regulations that limit the types of patents that NDA holders can list in the Orange Book, it has become common for brand companies to list any and every patent they can obtain in the Orange Book—regardless of the patent's scope or validity.

27. The FDA employs no adjudicatory or other process to determine whether a patent submitted by an NDA holder qualifies for listing under the applicable regulations. Because the FDA lacks the resources and

expertise to review the submitted patents, it must rely entirely on the good faith of the NDA holder submitting a patent for listing. *See* 59 Fed. Reg. 50,338, 50,343 (Oct. 3, 1994) ("FDA does not have the expertise to review patent information . . ."). As a result, courts recognize that the FDA's role in the patent listing process is purely ministerial.

Generic Drugs

28. Generic drugs are drugs that the FDA has found to be pharmaceutically equivalent and bioequivalent to a corresponding brand name drug. A drug is pharmaceutically equivalent compared with a brand name drug, if it contains the same active ingredient(s), is of the same dosage form, uses the same route of administration, is identical in strength and concentration, contains the same amount of active ingredient, and meets the same or compendial or other applicable standards. A drug is bioequivalent to a brand name drug if its active ingredient is absorbed at the same rate and to the same extent as the brand name drug.

29. Generic drugs are invariably priced substantially below the branded drugs to which they are pharmaceutically equivalent and bioequivalent. Typically, generic versions of brand name drugs are initially priced significantly below the brand name versions. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further. This price competition enables all

direct purchasers of a drug to (a) purchase generic versions of the drug at substantially lower prices, and/or (b) purchase the brand name drug at a reduced price.

30. In 1984, Congress enacted the Hatch-Waxman Act, which accelerates the approval process for generic drugs. Among other things, it permits a manufacturer seeking FDA approval for a generic drug to file an Abbreviated New Drug Application ("ANDA"). 21 U.S.C. § 355(j) (2005). An ANDA filer may rely on the safety and efficacy data previously provided in the NDA for its branded counterpart. FDA approval of an ANDA takes, on average, about 18 to 20 months.

31. FDA-approved generic drugs are certified by the FDA as pharmaceutically equivalent and bioequivalent to the branded drug, and are completely interchangeable with that branded drug. The FDA refers to such drugs as "AB-rated." A generic drug that is "AB-rated" may be dispensed by a pharmacist in lieu of its branded counterpart.

32. At the same time, the Hatch-Waxman Act also provides the brand-name manufacturer with various means to maintain or extend the market exclusivity for a brand name drug. For example, Hatch-Waxman grants the NDA applicant that receives approval for a New Chemical Entity an extra five (5) year period of exclusivity to market that drug. 21 U.S.C. § 355(c)(3)(D)(ii) (the "NCE exclusivity"). Pursuant to Hatch-Waxman, the FDA may not accept and start reviewing an ANDA application relating to the brand

name product during the 5-year NCE exclusivity period, unless the ANDA includes a Paragraph IV certification (described in more detail below), in which case such an ANDA may be filed after only four (4) years of the NCE exclusivity period. *See* 21 U.S.C. § 355(j)(5)(D)(ii).

33. Hatch-Waxman also created a procedure by which a brand-name manufacturer can delay the final approval and market entry for a generic drug for up to thirty months while patent infringement issues are being litigated in the courts. If a patent for a brand-name drug is listed in the Orange Book, then any competitor seeking to sell a generic equivalent of the brand-name drug claimed by the listed patent, must include with its ANDA application one of the following four certifications regarding each listed patent:

a. a certification that no patent for the brand-name drug has been filed with the FDA (a "paragraph I certification");

b. a certification that the patent for the brand-name drug has expired (a "paragraph II certification");

c. a certification that the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "paragraph III certification"); or

> d. a certification that the patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "paragraph IV certification").

21 U.S.C. § 355(j)(2)(A)(vii).

34. If a generic manufacturer files with its ANDA a paragraph IV certification asserting that the patent listed in the Orange Book in connection with the brand-name drug is invalid or will not be infringed by the proposed generic product, the ANDA applicant must promptly give notice of this fact to both the NDA holder and the owner of the patent(s) at issue.

35. Filing a paragraph IV certification with the FDA constitutes a "technical act of infringement" under Hatch-Waxman, which creates jurisdiction in the federal courts to entertain a patent infringement action, and gives the NDA holder forty-five (45) days from the date of the notice to institute such an action against the generic manufacturer under 35 U.S.C. § 271(e)(2). *See* 21 U.S.C. § 355(j)(5)(B)(iii). If a patent infringement action is initiated, FDA approval of the ANDA is automatically stayed for up to thirty months. 21 U.S.C. § 355(j)(5)(B)(iii).

36. If the NDA holder fails to initiate a patent infringement action within 45 days after receiving the generic manufacturer's paragraph IV certification, then the FDA may finally approve the generic manufacturer's

ANDA once the FDA is satisfied that the generic is equivalent to the brand name drug. If, however, the NDA holder initiates an infringement action against the ANDA filer within 45 days, then the FDA may not finally approve the ANDA until the earlier of either 30 months or the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). While the paragraph IV certification notice creates a jurisdictional basis for a patent infringement suit, an NDA holder cannot legitimately file a patent infringement claim against an ANDA applicant unless there is a legitimate factual and legal basis for such claim.

37. Moreover, if the NDA holder wishes to do so, it can refrain from filing a lawsuit within 45 days, wait for the generic to obtain final FDA approval and enter the market, and then file suit. Under those circumstances, the NDA holder would need to carry its normal burden to obtain a preliminary injunction against the generic company.

38. Brand-name manufacturers have a strong incentive to list any and every patent they can obtain in the Orange Book in order to trigger paragraph IV certifications and to file patent infringement suits against ANDA filers. There mere filing of an infringement action in response to a paragraph IV certification, regardless of the action's underlying merit, gives the brand-name company the functional equivalent of a self-effectuating preliminary injunction blocking the entry of a generic competitor. Indeed, as a practical

matter, the brand-name company wins the lawsuit simply by filing it because the filing automatically protects the company's monopoly for up to two-and-a-half years while the patent infringement action grinds through the court system.

39. An improper Orange Book listing also has additional anti-competitive effects because the first generic company to file an ANDA with a paragraph IV certification is, upon FDA approval, granted a 180-day period of exclusivity in relation to other generic manufacturers. 21 U.S.C. § 355(j)(5)(B)(iv). This 180-day exclusivity against other generic competitors is awarded to the first paragraph IV filer regardless of whether or not the brand company institutes pre-approval patent infringement litigation in response to the paragraph IV certification. Absent an improper Orange Book listing, no paragraph IV certification would be required, and thus, no generic company would receive 180-day exclusivity.

40. Defendants were at all times fully familiar with their ability to delay the entry of generic competition by the improper manipulation of the patent listing and pre-approval litigation provisions of the Hatch-Waxman Act.

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DEFENDANTS' OVERARCHING SCHEME TO DELAY GENERIC ENTRY

41. In order to forestall competition and protect their monopoly, Defendants engaged in an unlawful, exclusionary scheme involving (1) fraud and/or inequitable conduct on the PTO; (2) improper Orange Book listings; (3) sham patent infringement litigation against competitors; and (4) a sham citizen petition filed with the FDA. Defendants' conduct as a whole resulted in an unlawful creation and extension of their monopoly in desmopressin acetate tablets.

Defendants Worked Closely Throughout the Overarching Scheme

42. For over three decades, Aventis (and/or its corporate predecessors) have had a close working relationship with Ferring. During this time, Aventis (and/or its corporate predecessors and subsidiaries) have acted as Ferring's partners and/or agents regarding the sale of desmopressin products in the United States and elsewhere. As Ferring states on its website regarding its "Current Partners":

> Commercial Partners
>
> The development from a small, research-driven pharmaceutical company in the 1950s into the global mid-sized pharmaceutical company that Ferring is today has been well supported by various commercial

partnerships. Some of Ferring's key commercial partnerships are:

Aventis has been marketing Ferring's flagship MINIRIN in the US since the 1970s.

Minirin is one of the brand names for Ferring's desmopressin products.

43. Ferring obtained Patent No. 3,454,549 (the " '549 Patent") in 1969 and Patent No. 3,497,491 (the " '491 Patent") in 1970. The '549 Patent claimed the compound and process of making a synthetic version of the naturally-occurring human hormone, vasopressin, which has an anti-diuretic effect. The '491 Patent claims the polypeptide of vasopressin functioning as a targeted anti-diuretic for the treatment of diabetes insipidus.

44. In 1977, Ferring received approval from the FDA to market an intranasal formulation of DDAVP as an anti-diuretic. Ferring exclusively licensed the right to market and sell its patented compound in the United States to Rorer, one of Aventis's corporate predecessors. In the late 1970s and/or early 1980s, Rorer filed an NDA to sell Ferring's DDAVP nasal solution in the United States. That NDA application was approved at some time prior to 1982, and sometime thereafter Rorer began selling in the United States a desmopressin nasal solution manufactured by Ferring.

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45. In the late 1970s and/or early 1980s, Rorer filed an NDA to sell an injectable form of Ferring's desmopressin product in the United States. That NDA application was approved on or about March 30, 1984, and sometime thereafter Rorer began selling in the United States an injectable form of desmopressin manufactured by Ferring.

46. During the 1980s, Ferring and Aventis's corporate predecessors sold tens of millions of dollars in desmopressin products in the United States. It was foreseeable to Ferring and Aventis's corporate predecessors that the revenues and profits from the injectable and nasal solution forms of DDAVP would fall substantially once generic forms of those products entered the market after the expiration of the patents.

47. In an apparent effort to either (a) offset the expected financial decline that would occur once Ferring's existing desmopressin products faced competition, and/or (b) generally increase their revenues and profits from desmopressin products, the Defendants undertook the scheme alleged herein, surrounding the development and marketing of a desmopressin acetate tablet. This scheme involved inequitable conduct and/or fraud on the PTO, improper Orange Book listings, sham litigation, and a sham citizen petition.

48. By 1989 — one year before the patents on the other desmopressin products expired — Ferring and Rorer had already submitted an NDA to obtain FDA approval for a desmopressin tablet. A tablet form of

desmopressin for swallowing has obvious and distinct advantages over other forms (such as a nasal spray) including greater convenience, ease of use and administration, elimination of unpleasant taste and smell, and consequent patient appeal and compliance. Such a tablet form of desmopressin would not be (and is not) AB-rated to non-tablet forms.

49. However, by this time Ferring's application for a U.S. patent that would claim desmopressin tablets had already been rejected twice. It was foreseeable to Defendants that if they did not receive a patent for desmopressin tablets, competitors would be able to sell their own or generic versions sooner than they would otherwise if patent protection was obtained. Thus, Defendants were willing to seek FDA approval to market desmopressin tablets without patent protection, but the prospect of such protection provided strong financial incentives for Defendants to obtain a patent by any means, including fraud.

Defendants Procure '398 Patent Through Fraud and/or Inequitable Conduct on the PTO

50. Rules governing patent prosecution impose a duty of candor and good faith on those dealing with the PTO, "which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56. The rule provides: "Information is material to patentability when it is not cumulative to information already of record or being made of record in the

application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (i) Opposing an argument of unpatentability relied on by the Office, or (ii) Asserting an argument of patentability." Prior to 1992, the rule also provided that "information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." 37 C.F.R. § 1.56(a)(1991).

51. As explained more fully below, Ferring knowingly provided false and misleading information to the PTO in order to overcome the PTO's legitimate rejection of Ferring's attempt to claim an invention that was obvious and anticipated by the prior art.

52. On December 17, 1985, Ferring filed an application (serial no. 809,937) with the PTO that ultimately issued as the '398 patent (" '398 patent application"). The '398 patent application attempted to patent a gastro-intestinally absorbable form of DDAVP, *i.e.*, a tablet form of desmopressin acetate. If successful, the '398 patent application would have given Ferring renewed exclusivity in the sale of desmopressin products because Ferring would be the only company allowed to market the tablet form of desmopressin acetate.

53. The two inventors listed on the '398 patent application are Dr. Hans Vilhardt, a former research

director at Ferring, and Mr. Helmer Hagstam, who was then the technical director at Ferring. The inventors assigned their rights in the application to Ferring on May 21, 1984.

54. On May 28, 1986, Dr. Vilhardt and his attorney appeared at a preliminary interview with the PTO examiners to discuss the '398 patent application and prior art—in particular, U.S. Patent No. 3,497,491 ("Zaoral" or " '491 Patent") and U.S. Patent No. 3, 454,549 ("Boissanas" or " '549 Patent").

55. Ferring was the exclusive licensee of the Zaoral patent until its expiration in 1987. The Zaoral patent taught that "1-deamino-8-D-arginine vasopressin" "may be used . . . for . . . peroral . . . application." '491 Patent at col. 3 1.15-23, col. 5 1.15-20. The examiners were concerned that the Zaoral patent's disclosure of "peroral" (through the mouth) application of the peptide may have suggested the oral administration of the peptide for gastrointestinal absorption.

56. The examiner's written summary of the interview states that Dr. Vilhardt and his attorney argued to the examiner "that prior art does not teach administration via stomach route and that peroral implies 'buccal' [through the cheek] etc., and that one skilled in the art would not think otherwise." It also states that the applicants agreed to "consider amending the claims and filing declarations" and the examiner agreed to wait two weeks before giving a first action. The examiner also asked that the applicants to obtain

evidence from a non-inventor to show that the '398 patent was not obvious in light of the prior art.

57. The PTO examiners were aware that Ferring was the exclusive licensee of the '491 patent, which was soon to expire, and had an interest in convincing the PTO that the '398 patent application disclosed an invention not disclosed in the '491 patent. Therefore, they were concerned about the objectivity of those providing declarations and their relationship to Ferring.

58. Given the examiner's request for non-inventor declarations, Ferring was on notice that it needed to submit declarations from disinterested persons, and knew or should have known that a declarant's affiliations with the applicant were material.

59. On June 12, 1986, Ferring submitted a preliminary amendment with four declarations, including two from Vilhardt himself, one from Dr. Myron Miller, and one from Dr. Paul Czernichow. These declarations each relayed the declarant's scientific belief that the term "peroral" in the '491 patent meant that the compound could be administered "through the mouth," but only for absorption through the cheek (buccal) or under the tongue (sublingual).

60. Dr. Czernichow's declaration and accompanying curriculum vitae failed to disclose that he had received research funding from Ferring from 1985 to 1986 to conduct a clinical investigation relating to a particular DDAVP preparation.

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61. At some point during the '398 patent prosecution, Dr. Vilhardt also sought, but never submitted, declarations from two other Ferring consultants, Professor Leonard Share and Professor Besser.

62. Despite the four declarations submitted with Ferring's amendment, on November 20, 1986, the PTO rejected the '398 patent application as anticipated by or obvious in light of the Zaoral Patent. The rejection stated: "As Applicants are the exclusive licensee of the Zaoral patent, it is obviously expeditious for Applicants to argue that 'peroral' referred to in the [Zaoral] patent referred only to sublingual or buccal routes, whereas the instant mode of administration excludes such routes as it involves absorption by the gastrointestinal tract."

63. On May 20, 1987, Ferring filed a request for reconsideration, arguing that the '491 patent did not teach the claims of the '398 patent application.

64. On August 14, 1987, the PTO again rejected the '398 patent application based on prior art.

65. On September 21, 1990, the Board of Patent Appeals and Interferences affirmed the examiner's rejection of the '398 patent application, concluding that the "peroral" recitation in the '491 patent coupled with the knowledge of the prior art disclosed in a 1974 study conducted by Vavra was suggestive of and anticipated the oral administration of DDAVP for gastrointestinal absorption in humans. The Vavra study involved the

administration of desmopressin to rats by stomach gavage and showed that DDAVP caused antidiuresis in rats. However, because the examiners had not relied on the Vavra reference, the Board designated its decision as "a new rejection under the provisions of 37 C.F.R. § 1.196(b)," and explained that the applicant could elect to have further prosecution before the examiner in response to the new rejection.

66. On November 21, 1990, Ferring filed an Amendment after Appeal with the PTO. In support of its amendment, Ferring submitted declarations from Drs. Vilhardt, Miller, and Czernichow, as before, and from Dr. Ian Robinson and Dr. Tomislav Barth, to support its argument that the invention disclosed in the '398 patent application was not obvious despite the prior art. Each of these declarations explained why, in the declarant's own professional judgment, the Vavra reference did not suggest that DDAVP could be absorbed through the gastrointestinal tract.

67. Ferring did not disclose to the PTO that four of the five declarations submitted to the PTO were written by scientists who had been employed by, or had received research funds from Ferring. Nor did it disclose that Dr. Vilhardt had participated in the drafting of two of the four declarations submitted by non-inventors. The examiners were not and could not have otherwise been aware of the declarants' relationships with Ferring.

68. As with the declaration submitted with the first '398 patent application, Ferring did not inform the PTO of Dr. Czernichow's affiliation with Ferring.

69. Ferring failed to inform the PTO that Dr. Robinson (one of the new declarants): (1) had been Ferring's pre-clinical research director from 1985 to 1986; (2) had been a paid consultant for Ferring from 1986-1989; (3) while Robinson was the research director at Ferring, Ferring was funding Vilhardt's research involving DDAVP tablets; and (4) Ferring had sponsored a research program in Dr. Robinson's laboratory for about three years.

70. Ferring also did not tell the PTO that, at the time Dr. Robinson submitted his declaration, he had no expertise in DDAVP tablets, that he did not recall having done any research on drug delivery systems or on the absorption of peptides in the gastrointestinal tract—two issues central to understanding whether the '398 patent was obvious in light of the prior art—and that he did not understand why he was retained to provide a declaration on DDAVP tablets.

71. Ferring's documents identify Dr. Barth (another new declarant) as a Ferring consultant. However, Ferring did not submit Dr. Barth's CV with his declaration, and did not disclose that Dr. Barth worked on several projects funded by Ferring between 1984 and 1987, and that he worked intermittently with Vilhardt on some projects between 1988 and 2000.

72. Ferring knew that it should have revealed the declarants' relationships with Ferring and/or interest in the '398 patent application because the Manual of Patent Examining Procedure in effect at that time stated: "Affidavits or declarations should be scrutinized closely and the facts presented with care. The *affiant's or declarant's interest is a factor which may be considered.*" (emphasis added).

73. On April 8, 1991, — after three rejections — the PTO issued a Notice of Allowability, allowing the '398 patent to issue.

74. The declarations Ferring submitted in support of its '398 patent application were highly material, and the failure to disclose the relationship of the declarants with Ferring was likely done with an intent to deceive. Had the PTO examiners been aware of the relationships and affiliations of the declarants, they would not have accorded the declarations much weight, and the '398 patent would not have issued.

Defendants Improperly List The '398 Patent in the Orange Book

75. Ferring licensed to Aventis the right to market and sell the invention of the '398 patent.

76. Despite knowing that the '398 patent had been procured by fraud or inequitable conduct, Defendants caused the '398 patent to be listed in the Orange Book. The Orange Book listing for the '398 patent was

fraudulent because: (a) the fraudulently obtained, invalid '398 patent could not claim a tablet form of DDAVP, and (b) a claim of infringement of the fraudulently obtained, invalid '398 patent could not reasonably be asserted against a person who engaged in the unlicensed manufacture, use, or sale of the drug.

77. If the '398 patent had not issued, Defendants would not have been able to list it in the Orange Book, nor would Defendants have been able to file suit(s) for patent infringement against potential competitors. In that event, Defendants would not have been able to invoke the 30-month stay of Hatch-Waxman.

78. Furthermore, absent the fraudulent Orange Book listing, none of the generic competitors would have filed Paragraph IV certifications regarding the '398 patent, and thus: (a) there would be no 180-day exclusivity for the first ANDA applicant; and (b) multiple generic competitors would have been able to enter the market at or about the same time, rather than having to wait for the 180-day exclusivity to expire.

79. As a result of the Orange Book listing, no generic manufacturer could submit an ANDA to the FDA, seeking approval to market a generic version of DDAVP in the United States without certifying either that its product would not be marketed in the United States until the expiration of each listed patent (paragraph III certification) or that each listed patent was invalid or not infringed by the proposed product (paragraph IV certification).

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80. Before Ferring had obtained a patent for desmopressin acetate tablets, Aventis had filed an NDA with the FDA for approval of that product. Once the '398 patent issued, Aventis amended its NDA to add a false and fraudulent Orange Book listing certification relating to the '398 patent.

81. Given the long and close business relationship among Defendants, including with respect to DDAVP, Ferring knew or likely knew about Aventis's actions regarding the NDA application and the Orange Book listing. Because Ferring knew that the '398 patent had been obtained fraudulently, Ferring therefore also knew or likely knew that Aventis's representations to the FDA regarding the listing of the '398 patent in the Orange Book were also false and misleading, for the reasons alleged herein.

82. The FDA approved Aventis's NDA on September 6, 1995. Shortly thereafter, Aventis began marketing desmopressin acetate tablets under the brand name DDAVP. Aventis's U.S. sales of DDAVP tablets were approximately $78 million in 2000, $98 million in 2001, $125 million in 2002, $157 million in 2003, and $180 million in 2004.

83. In the absence of the fraudulently obtained '398 patent, other pharmaceutical companies could have sought and obtained FDA approval for their own versions of desmopressin tablets without having to undertake the burden and expense of investigating the '398 patent and being sued for patent infringement.

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84. In the absence of the fraudulently or inequitably obtained '398 patent, and in light of existing sales of non-tablet forms of desmopressin (more than $70 million in 1995), one or more other pharmaceutical companies likely would have launched their own competing desmopressin tablets to compete with Defendants' DDAVP tablets, via, for example, an ANDA paragraph I certification.

85. By obtaining the '398 patent through fraud, Defendants eliminated this avenue of competition and forced potential competitors to, instead, undertake the burden and expense of investigating and challenging the '398 patent, via an ANDA paragraph IV certification and concomitant patent litigation, if they wished to sell desmopressin tablets before expiration of the '398 patent.

Defendants File Sham Litigation

Barr Litigation

86. In July 2002, Barr Laboratories, Inc. ("Barr") submitted to the FDA ANDA No. 76-470 to obtain approval to market a generic version of 0.1 and 0.2 mg DDAVP tablets. Barr's ANDA contained a paragraph IV certification that the '398 patent is invalid, unenforceable, and/or would not be infringed by Barr's generic product.

87. On or about October 29, 2002, Barr sent Defendants notice that Barr's ANDA had been received by the FDA and that the ANDA contained a paragraph IV certification.

88. On December 13, 2002, Defendants filed a patent infringement action against Barr in the United States District Court for the Southern District of New York. As Defendants had intended because they listed the '398 patent in the Orange Book, their patent infringement suit against Barr resulted in an automatic 30-month stay of final FDA approval of Barr's ANDA. Barr could not receive final FDA approval until it either prevailed in the patent infringement suit, or the expiration of thirty months, whichever occurred first. Thus, the mere filing of Defendants' sham lawsuit prevented a generic form of desmopressin acetate tablets from entering the market, thereby illegally extending Defendants' monopoly.

89. At the time Defendants' filed their infringement action against Barr, they knew that a claim of infringement could not be reasonably asserted against a person who engaged in the unlicensed manufacture, use, or sale of the drug because they knew the patent was invalid, unenforceable, and/or that it had been obtained through fraud and/or inequitable conduct.

90. On February 7, 2005, the United States District Court for the Southern District of New York granted summary judgment to Barr, holding that Ferring had committed inequitable conduct by deliberately deceiving the PTO about the non-inventor declarations submitted with the '398 patent application. The court found "clear and convincing evidence of an intent to mislead the examiners" and that "the deceit was practiced over a long period of time by more than one person and

appears to have been outcome determinative." *See Ferring B.V. v. Barr Labs., Inc.*, No. 02 Civ. 9851, 2005 WL 437981, at *10 (S.D.N.Y. Feb. 7, 2005). On the key issue of "but for" causation, the court found that "the PTO must have relied substantially on these declarations, as there is no alternative explanation offered for the Board's final allowance of the claims after several prior rejections by the PTO." *Id.* at *9-10. The District Court opinion was the first finding that Defendants had committed fraud on the PTO in obtaining the '398 patent and it publicly revealed Defendants' anticompetitive conduct.

91. On February 15, 2006, the United States Court of Appeals for the Federal Circuit affirmed the district court's grant of summary judgment on the issue of inequitable conduct. First, the Federal Circuit held that Defendants' failure to disclose the relationships between the "non-inventor" declarants and Ferring was "highly material as a matter of law" because the PTO examiners had specifically requested "non-inventor" affidavits and had expressly stated that they were concerned about the objectivity of those trying to distinguish the '491 patent from the invention claimed in the '398 patent application. *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1189-90 (Fed. Cir. Feb. 15, 2006). Second, the court found that the omission was made with the intent to deceive because the record established that the applicant knew of the information (i.e., relationships with Ferring), the applicant knew or should have known of the materiality of that information, and the applicant had not provided a credible explanation for the

withholding. The court concluded that "at least where the objectivity of the declarant is an issue in the prosecution [of the patent], the inventor must disclose the known relationships and affiliations of the declarants so that those interests can be considered in weighing the declarations." *Id.* at 1195.

92. By suing Barr under the Hatch-Waxman Act, Defendants delayed FDA approval of generic desmopressin acetate tablets by (1) provoking, in effect, a moratorium or a slow track on the FDA's consideration of Barr's ANDA and/or (2) undermining Barr's vigorous pursuit of its application.

93. The FDA receives numerous ANDAs per year and prioritizes those drug applications that are not subject to patent litigation. In the absence of Defendants' sham litigation, the FDA would have focused more attention on Barr's ANDA and would have granted approval earlier than July 1, 2005.

94. In addition, the sham litigation forced Barr to divert resources away from the FDA approval process and towards defending itself against Defendants' claims of patent infringement and undermined incentives to obtain rapid FDA approval since, for example, the 30-month stay under the Hatch-Waxman Act had been triggered.

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Teva Litigation

95. Sometime after July 2002, Teva Pharmaceuticals USA, Inc. ("Teva") also submitted an ANDA application to the FDA to sell a generic version of desmopressin acetate tablets.

96. On or about June 9, 2004, Ferring received notice that Teva had filed an ANDA with a paragraph IV certification seeking to market a generic version of desmopressin acetate tablets.

97. On July 20, 2004, Defendants filed a patent infringement action against Teva in the United States District Court for the District of Delaware. As with the Barr litigation, Defendants commenced and maintained this lawsuit even though it was (1) objectively baseless, in that no reasonable litigant could ultimately expect success on the merits given Defendants' fraud and/or inequitable conduct on the PTO; and (2) motivated by a desire to impose injury on Teva, a potential competitor, rather than to obtain justifiable legal relief.

98. By suing Teva under the Hatch-Waxman Act, Defendants delayed FDA approval of generic desmopressin acetate tablets by (1) provoking, in effect, a moratorium or a slow track on the FDA's consideration of Teva's ANDA and/or (2) undermining Teva's vigorous pursuit of its application.

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Defendants Use A Sham Citizen Petition To Further Delay Generic Entry

99. Under the citizen petition process, anyone may request or petition the FDA to change or create an agency policy or regulation under 21 C.F.R. Part 10.30. The FDA must respond within 180 days by either approving or denying the petition or by providing a tentative response indicating why it has been unable to reach a decision.

100. The citizen petition process may slow down approval of a drug because the FDA customarily evaluates an ANDA and a related citizen petition at the same time. The FDA is reluctant to approve a generic drug ANDA before acting on a citizen petition addressing the particular ANDA.

101. FDA regulations require that the party submitting the citizen petition certify that the petition "includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition."

102. Recently, the FDA's Chief Counsel, Sheldon Bradshaw, sought industry suggestions on the citizen petition process at the first annual Generic Pharmaceutical Association Law and Policy Conference in Washington, D.C. on September 19, 2005. Bradshaw stated that "[o]ne of the things [he had] learned in [his] short time at the agency is that there's been a bit of a

breakdown in this citizen petition process." Bradshaw observed that some citizen petitions seemed designed not to bring timely scientific or regulatory concerns to the agency's attention, but rather to delay action on a competitor's drug product by forcing the FDA to take time to analyze the issues raised in the petition when those issues are either not new or have been known to the petitioner for years before filing the petition.

103. One suggestion that has been made by the Generic Pharmaceutical Association is to separate the generic drug approval process from the process for ruling on citizen petitions in order to remove the incentive for filing frivolous petitions.

104. In early 2004, Defendants' patent infringement action against Barr was entering the summary judgment stage. Because Defendants had no objectively reasonable basis for filing the infringement action and their only intent in filing that action was to delay generic entry, Defendants likely knew or reasonably should have known that the district court would rule in favor of Barr, thus paving the way for FDA approval of Barr's ANDA.

105. In order to further delay FDA approval, Ferring filed a sham citizen petition on February 2, 2004 (Docket No. 2004P-0068/CP1). Ferring did not have a reasonable basis for filing the petition, and its only purpose and intent was to delay the entry of generic competitors into the market. Furthermore, Ferring's use of the citizen petition was an attempt to interfere directly with the business relationships of their generic

competitors through the use of governmental process — as opposed to the outcome of that process — as an anticompetitive weapon. At all relevant times, Defendants were aware that they could delay approval of Barr's generic ANDA by filing a citizen petition relating to ANDAs for oral desmopressin tablets.

106. Ferring wanted the FDA to require Barr to conduct and submit more tests — pharmacodynamic ("PD") studies measuring urine osmolarity — in order for Barr to establish the bioequivalence of Barr's desmopressin product to DDAVP. These new studies would have been in addition to the conventional pharmacokinetic (PK) tests measuring blood plasma concentration which Barr had already submitted to the FDA. In Ferring's purported opinion, the conventional PK bioequivalence tests did not adequately address safety and efficacy of oral desmopressin therapy for nocturnal enuresis in children. Thus, in its citizen petition, Ferring requested that ANDAs for generic oral desmopressin products include: (1) evidence from comparative clinical studies demonstrating bioequivalence to DDAVP in terms of both conventional PK blood plasma concentration measurements, as well as studying PD properties by measurement of urine osmolarity and flow rates in water-loaded enuretic (bed wetting) children; (2) if bioequivalence was not established by such PK and PD studies, evidence from comparative clinical trials demonstrating safety and efficacy equivalent to DDAVP in enuretic children; and (3) separate bioequivalence evidence for each dose level.

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107. In support of its petition, Ferring cited to several allegedly unique aspects of the drug, including (1) novel issues regarding variations in bioavailability, such as low effective plasma concentrations and high inter- and intra-subject variability; and (2) the fact the drug was intended for use in children, making the data from adults, purportedly insufficient to establish safety and efficacy.

108. As reflected in the FDA's rejection of the petition, discussed more fully below, Ferring's arguments had no basis in science, fact, FDA regulations or Guidance. The only goal in submitting the citizen petition was to preserve Defendants' monopoly in desmopressin acetate tablets. Given the FDA's limited resources and competing priorities, it was foreseeable or likely that even a frivolous citizen petition would cause delay. Indeed, on July 30, 2004, the FDA informed Ferring that it "ha[d] been unable to reach a decision on [its] petition due to the need to address other Agency priorities" and that the FDA would respond "as soon as possible given the numerous demands on the Agency's resources."

109. Ferring's citizen petition certified "that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition."

110. Nonetheless, the petition did not include information from a study sponsored by Defendant Aventis, which was unfavorable to the positions advanced by the petition. *See* Argenti, D., et al., *A Pharmacokinetic and Pharmacodynamic Comparison of Desmopressin Administered as Whole, Chewed, and Crushed Tablets, and as an Oral Solution*, J. Urology, Vol. 165, 1446 (May 2001) (the "Aventis Study").

111. The Aventis Study results demonstrated that, regardless of the formulation of desmopressin tested, the PK and PD responses observed were very similar. Thus, the type of tests which Ferring sought to require Barr to conduct would have been redundant at best, and caused needless delay in the approval of Barr's ANDA.

112. Ferring knew or should have known of the Aventis Study and yet did not disclose it in the citizens petition to the FDA. Aventis knew of its study and knew or should have known that the citizens petition was being filed without citing the Aventis Study, and yet let Ferring omit the Aventis Study from the citizens petition.

113. After the district court's grant of summary judgment to Barr in the patent litigation, on March 8, 2005, Barr submitted a response to the lengthy citizen petition, addressing each of the issues Ferring had raised. Barr pointed out that the "FDA repeatedly has affirmed that PK studies are the gold standard for establishing bioequivalence, particularly for orally

administered, systematically acting drug products, such as desmopressin." Barr also called the Aventis Study to the attention of the FDA, and stated that the "results [of the Aventis Study] explain why Ferring, and not the NDA-holder Aventis, submitted the instant citizen petition."

114. In its regulations, the FDA lists "in descending order of accuracy, sensitivity and reproducibility" the types of evidence that the agency will accept to establish bioequivalence. 21 C.F.R. § 320.24(b). The first and best option is a PK study, such as the one Barr had already included in its ANDA. According to the FDA's hierarchy of tests, the studies suggested by Ferring are the least accurate, sensitive, and reproducible tests of all.

115. On July 1, 2005, the FDA rejected Ferring's citizen petition, stating that Ferring had "offer[ed] no convincing evidence (i.e. data or other information) that any of your proposed changes are needed. ***Accordingly, not having been presented with any basis for departing from our long-established and well-settled practice, we deny your petition in its entirety.***" (emphasis added). The FDA also discussed each of Ferring's baseless claims, rejecting each in turn.

116. First, the FDA found no additional studies beyond conventional PK studies were required to be submitted with Barr's ANDA. The FDA concluded that "in the case of products like oral demopressin that are intended for systemic distribution within the body, and for which drug concentration levels can be measured in

blood plasma, the additional data [Ferring] request[ed] would be expected to be ***inferior*** to the measurement of plasma drug levels for establishing BE. [Ferring] fail[ed] to present . . . evidence either to refute this conclusion as to the additional data's inferiority, to demonstrate that conventional BE testing is inadequate, or to show that its augmentation by the additional data would enable more accurate determination of BE for generic oral desmopressin products than would conventional testing alone." (italics in original). Furthermore, the FDA found that it would expect that the duration of clinically significant action between DDAVP tablets and Barr's generic desmopressin tablets would be the same. Ferring "presented no evidence to refute this conclusion" and the FDA saw "no substantiated reason to believe" Ferring's argument regarding length of action.

117. Second, the FDA rejected Ferring's request for additional tests on children because Ferring had "articulated no scientifically substantiated reason — nor [was the FDA] aware of any, based on available data concerning desmopressin and other drugs — why a generic oral desmopressin product shown to be bioequivalent to DDAVP in healthy adults would not be bioequivalent to this [reference listed drug] in the approved pediatric population."

118. Finally, the FDA concluded there was no need for separate bioequivalence evidence for each dose level because "the data in DDAVP's NDA failed to adequately test, let alone demonstrate, a lack of proportionality in

drug exposure between the two strengths of DDAVP, and [Ferring had] not provided (nor [was the FDA] aware of) other data demonstrating such a lack of proportionality." The FDA generally waives studies for the lower strength if bioequivalence is established for the higher strength.

119. The FDA repeatedly cited the Aventis Study in its response to support its conclusion that Ferring's request for additional data was baseless. The FDA noted that although Ferring was required to attest that it had included information known to be unfavorable to the petition:

> Notably, the Petition also fail[ed] to disclose or describe a published study conducted by Aventis, the sponsor of the DDAVP NDA, on various desmopressin formulations that appears inconsistent with [Ferring's] position that pharmacodynamic or other clinical studies are needed to establish the [bioequivalence] of oral desmopressin products (. . . this study also appears inconsistent with [Ferring's] position in other respects). The Petition, in fact, does not cite any studies unfavorable to [Ferring's] arguments.

120. Ferring's omission of the Aventis Study is further evidence that the citizen petition was a sham.

121. On July 1, 2005 — the same day the FDA rejected Ferring's citizen petition — the FDA granted final approval of Barr's ANDA for generic desmopressin tablets. Absent Ferring's sham citizen petition, the FDA would have approved Barr's ANDA at an earlier date.

122. On July 15, 2005, Barr launched its generic version of desmopressin acetate tablets although Defendants' patent suit remained pending. Because Barr was the first ANDA filer, under Hatch-Waxman, it received a 180-day exclusivity period. Thus, as a result of Defendants' anticompetitive conduct described above, no other generic manufacturers could enter the market until Barr's exclusivity period had run.

123. On January 25, 2006, the FDA approved Teva's ANDA, and Teva began selling generic desmopressin tablets in January 2006. Teva, too, launched while the patent litigation was still pending.

124. On March 7, 2006, the FDA approved Apotex's ANDA, seeking to market a generic version of desmopressin acetate tablets. Apotex's market entry is expected shortly.

125. But for Defendants' illegal conduct, generic competitors would have begun marketing generic versions of DDAVP tablets much earlier.

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MONOPOLY POWER

126. Defendants have monopoly power with respect to DDAVP tablets and its AB-rated generic equivalents. Insofar as proof of a relevant market is required, the relevant product market is desmopressin acetate tablets and any AB-rated generic equivalents.

127. A significant non-transitory price increase for desmopressin acetate tablet products would not have caused significant loss of sales to non-desmopressin acetate tablet products.

128. The relevant geographic market is the United States and its territories.

129. Defendants' actions as part of, and in furtherance of, the illegal monopolization alleged herein, were authorized, ordered, or done by Defendants' officers, agents, employees, or representatives while actively engaged in the management of Defendants' affairs.

130. Defendants' illegal acts to prevent the introduction into the U.S. marketplace of any generic versions of DDAVP tablets resulted in Plaintiffs and members of the Class paying more than they would have paid for desmopressin tablets absent Defendants' illegal conduct. But for Defendants' illegal conduct, generic competitors would have begun marketing generic versions of DDAVP tablets much earlier.

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ANTICOMPETITIVE EFFECTS

131. Defendants' exclusionary conduct has enhanced and maintained Defendants' monopoly power by preventing generic entry into the relevant market and unlawfully enabled Defendants to sell DDAVP tablets without being subject to generic competition.

132. If generic competitors had been able to enter the market sooner, Plaintiff and other members of the Class would have purchased approved generics instead of the higher-priced brand-name drug for some or all of their desmopressin acetate tablet requirements and would have received discounts and/or have paid lower prices for some or all of any branded DDAVP tablet purchases. By preventing generic competitors from entering the market, Defendants caused Plaintiffs and other direct purchasers of DDAVP tablets to pay more for desmopressin acetate tablets than they otherwise would have.

133. Defendants' unlawful conduct, as alleged herein, not only caused delay in generic entry but delay in competition among generics. Absent Defendants' obtaining the '398 patent through fraud and/or inequitable conduct, fraudulent orange book listing, sham litigation and sham citizen petition, a generic desmopressin tablet would have received approval earlier, and any 180-day exclusivity period under Hatch-Waxman would have expired earlier than it did (or never would have been available at all). Had other generic competitors (such as Teva and Apotex) been able to

compete with their generic products sooner, the average price of desmopressin acetate tablets would have declined even further and more quickly.

DAMAGES

134. During the relevant period, Plaintiffs and members of the Class purchased substantial amounts of DDAVP tablets from one or more of the Defendants. As a result of the illegal conduct of Defendants, members of the Class were compelled to pay, and did pay, artificially inflated prices for their desmopressin acetate tablet requirements. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of the brand-name desmopressin acetate tablets was artificially inflated or maintained by Defendants' illegal conduct; and/or (2) class members were deprived of the opportunity to purchase lower-priced generic versions of desmopressin acetate tablets. As a consequence, members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges.

INTERSTATE TRADE AND COMMERCE

135. During all or part of the Class Period, one or more Defendants manufactured and sold substantial amounts of DDAVP in a continuous and uninterrupted flow of commerce across state and national lines and throughout the United States.

136. At all relevant times, DDAVP manufactured and sold by one or more Defendants was shipped across state lines and sold to customers located outside its state of manufacture.

137. During all or part of the Class Period, Defendants transmitted funds as well as contracts, invoices, and other forms of business communications and transactions in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of DDAVP.

138. In furtherance of its efforts to monopolize and/or restrain competition in the market for DDAVP and its generic equivalents, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel.

139. Defendants' efforts to monopolize and restrain competition in the market for DDAVP has substantially affected interstate and foreign commerce.

VIOLATIONS

Monopolization in Violation of Section 2 of the Sherman Act, 15 U.S.C. §2

140. Plaintiffs reallege and incorporate by reference all preceding paragraphs as if fully set forth herein.

141. At all relevant times, Defendants possessed monopoly power over the price of desmopressin acetate tablets in the United States. To the extent required by law, the relevant product market is desmopressin acetate tablets.

142. As a result of their monopoly power, Defendants have charged prices for desmopressin acetate tablets well above competitive prices. But for Defendants' exclusionary and anticompetitive conduct, as alleged herein, Defendants would not have created or maintained monopoly power.

143. Ferring and Aventis worked closely and in concert throughout the anticompetitive scheme alleged herein to create or maintain their monopoly power in the desmopressin acetate tablet market. Ferring and Aventis, singularly and jointly, each actively participated in all or most of the components of the exclusionary scheme alleged herein, and each benefited (and continued to benefit) from the scheme as alleged herein. Each acted in furtherance of the exclusionary scheme with the knowledge, assistance, and/or acquiescence of the other.

144. During the relevant period, Defendants knowingly, willfully, and unlawfully created and maintained their monopoly power by engaging in exclusionary conduct that discouraged rather than encouraged competition on the merits. As explained in detail above, Defendants engaged in an exclusionary scheme that included, *inter alia*, the following conduct:

a. Procuring the '398 patent by committing fraud and/or inequitable conduct before the PTO;

b. Improperly listing the fraudulently obtained '398 patent in the Orange Book;

c. Filing sham patent litigation against generic competitors in order to "trigger" the Hatch-Waxman automatic 30-month stay of FDA approval of the generic ANDAs; and

d. Filing a sham citizen petition to further delay FDA final approval of Barr's ANDA.

145. The goal, purpose, and/or effect of Defendants' scheme was to prevent, delay, and/or minimize the success of the entry of generic desmopressin acetate tablets. Generic desmopressin acetate tablets would have entered the market at prices significantly below Defendants' prices for DDAVP, which would have effectively caused the average market price of desmopressin acetate to decline dramatically.

146. The goal, purpose, and/or effect of Defendants' scheme was also to create, maintain, and extend Defendants' monopoly power with respect to desmopressin acetate tablets. Defendants' illegal scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace

of any generic version of DDAVP enable Defendants to continue charging supracompetitive prices for desmopressin acetate tablets without a substantial loss of sales.

147. Plaintiffs and members of the Class have been injured in their business and property by reason of Defendants' antitrust violations. Their injury consists of paying higher prices for desmopressin acetate tablets than they would have paid in the absence of those violations. Such injury, namely overcharges, is of the type antitrust laws were designed to prevent and flows from that which makes Defendants' conduct unlawful.

JURY TRIAL DEMANDED

148. Plaintiffs demand trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and members of the Class, respectfully request:

(i) Certification of this case as a class action;

(ii) Judgment declaring Defendants' actions as alleged herein to be a violation of Section 2 of the Sherman Act;

(iii) Judgment in favor of Plaintiffs and members of the Class against Defendants for damages representing three times the overcharge damages sustained by Plaintiff and other members of the Class;

(iv) Joint and several judgment be entered against each Defendants in favor of Plaintiffs and the other members of the Class;

(v) Pre- and post-judgment interest;

(vi) Costs of suit, including reasonable attorneys' fees; and

(vii) Such other and further relief as the Court deems just and proper.

Dated: March 31, 2006

COHEN, MILSTEIN, HAUSFELD & TOLL, P.L.L.C.

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APPENDIX E — RELEVANT STATUTES

28 USCS § 1295

§ 1295. Jurisdiction of the United States Court of Appeals for the Federal Circuit

(a) The United States Court of Appeals for the Federal Circuit shall have exclusive jurisdiction—

> (1) of an appeal from a final decision of a district court of the United States, the United States District Court for the District of the Canal Zone, the District Court of Guam, the District Court of the Virgin Islands, or the District Court for the Northern Mariana Islands, if the jurisdiction of that court was based, in whole or in part, on section 1338 of this title, except that a case involving a claim arising under any Act of Congress relating to copyrights, exclusive rights in mask works, or trademarks and no other claims under section 1338(a) shall be governed by sections 1291, 1292, and 1294 of this title;
>
> (2) of an appeal from a final decision of a district court of the United States, the United States District Court for the District of the Canal Zone, the District Court of Guam, the District Court of the Virgin Islands, or the District Court for the Northern Mariana Islands, if the jurisdiction of that court was based, in whole or in part, on section 1346 of this title, except that jurisdiction of an appeal

in a case brought in a district court under section 1346(a)(1), 1346(b), 1346(e), or 1346(f) of this title or under section 1346(a)(2) when the claim is founded upon an Act of Congress or a regulation of an executive department providing for internal revenue shall be governed by sections 1291, 1292, and 1294 of this title;

(3) of an appeal from a final decision of the United States Claims Court of Federal Claims;

(4) of an appeal from a decision of—

(A) the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office with respect to patent applications and interferences, at the instance of an applicant for a patent or any party to a patent interference, and any such appeal shall waive the right of such applicant or party to proceed under section 145 or 146 of title 35;

(B) the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office or the Trademark Trial and Appeal Board

with respect to applications for registration of marks and other proceedings as provided in section 21 of the Trademark Act of 1946 (15 U.S.C. 1071); or

(C) a district court to which a case was directed pursuant to section 145, 146, or 154(b) of title 35;

(5) of an appeal from a final decision of the United States Court of International Trade;

(6) to review the final determinations of the United States International Trade Commission relating to unfair practices in import trade, made under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337);

(7) to review, by appeal on questions of law only, findings of the Secretary of Commerce under U.S. note 6 to subchapter X of chapter 98 of the Harmonized Tariff Schedule of the United States (relating to importation of instruments or apparatus);

(8) of an appeal under section 71 of the Plant Variety Protection Act (7 U.S.C. 2461);

(9) of an appeal from a final order or final decision of the Merit Systems Protection Board, pursuant to sections 7703(b)(1) and 7703(d) of title 5;

(10) of an appeal from a final decision of an agency board of contract appeals pursuant to section 8(g)(1) of the Contract Disputes Act of 1978 (41 U.S.C. 607(g)(1));

(11) of an appeal under section 211 of the Economic Stabilization Act of 1970;

(12) of an appeal under section 5 of the Emergency Petroleum Allocation Act of 1973;

(13) of an appeal under section 506(c) of the Natural Gas Policy Act of 1978; and

(14) of an appeal under section 523 of the Energy Policy and Conservation Act .

(b) The head of any executive department or agency may, with the approval of the Attorney General, refer to the Court of Appeals for the Federal Circuit for judicial review any final decision rendered by a board of contract appeals pursuant to the terms of any contract with the United States awarded by that department or agency which the head of such department or agency has concluded is not entitled to finality pursuant to the review standards specified in section 10(b) of the Contract Disputes Act of 1978 (41 U.S.C. 609(b)). The

head of each executive department or agency shall make any referral under this section within one hundred and twenty days after the receipt of a copy of the final appeal decision.

(c) The Court of Appeals for the Federal Circuit shall review the matter referred in accordance with the standards specified in section 10(b) of the Contract Disputes Act of 1978. The court shall proceed with judicial review on the administrative record made before the board of contract appeals on matters so referred as in other cases pending in such court, shall determine the issue of finality of the appeal decision, and shall, if appropriate, render judgment thereon, or remand the matter to any administrative or executive body or official with such direction as it may deem proper and just.

Appendix E

28 USCS § 1338

§ 1338. Patents, plant variety protection, copyrights, mask works, designs, trademarks, and unfair competition

(a) The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents, plant variety protection, copyrights and trademarks. Such jurisdiction shall be exclusive of the courts of the states in patent, plant variety protection and copyright cases.

(b) The district courts shall have original jurisdiction of any civil action asserting a claim of unfair competition when joined with a substantial and related claim under the copyright, patent, plant variety protection or trademark laws.

(c) Subsections (a) and (b) apply to exclusive rights in mask works under chapter 9 of title 17, and to exclusive rights in designs under chapter 13 of title 17, to the same extent as such subsections apply to copyrights.

No. 09-1175

SUPREME COURT, U.S.
MAY 28 2010
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

FERRING B.V., FERRING PHARMACEUTICALS, INC., and AVENTIS PHARMACEUTICALS, INC.,

Petitioners,

v.

MEIJER, INC., MEIJER DISTRIBUTION, INC., ROCHESTER DRUG CO-OPERATIVE, INC., and LOUISIANA WHOLESALE DRUG CO., INC., on behalf of themselves and all others similarly situated,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

When Congress fashioned a court of appeals to adjudicate patent claims, it never intended to abrogate the traditional role of regional circuits to hear appeals in other cases, including antitrust cases. Jurisdiction for the U.S. Court of Appeals for the Federal Circuit was thus limited to cases in which a claim "arises under" federal patent law. In *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800 (1988), this Court held that if a plaintiffs' claims do not necessarily rely on patent law and can be supported by even a single non-patent theory instead, Federal Circuit jurisdiction is unavailable, and the regional circuit must hear the appeal. This Court also held that the mere presence of patent issues within a case would not suffice to afford the Federal Circuit jurisdiction.

The question presented is whether the Federal Circuit has jurisdiction for an appeal where the well-pleaded complaint stated a single claim for violation of the antitrust laws and sought relief under Section 4 of the Clayton Act, 15 U.S.C. § 15, and where the plaintiff's right to such relief does *not* necessarily depend on the resolution of a substantial question of federal patent law.

CORPORATE DISCLOSURE STATEMENT PURSUANT TO SUPREME COURT RULE 29.6

Respondents Meijer, Inc. and Meijer Distribution, Inc. hereby certify that Respondent Meijer, Inc. (a private non-governmental entity) is a privately held corporation, which is a wholly-owned subsidiary of Meijer Companies, Ltd.; Respondent Meijer Distribution, Inc. (a private non-governmental entity) is a privately held corporation, which is a wholly-owned subsidiary of Meijer, Inc.; and no publicly held corporation owns 10% or more of the stock of Meijer Inc. or Meijer Distribution, Inc.

Respondent Rochester Drug Co-Operative, Inc. certifies that Rochester Drug Co-Operative, Inc. has no corporate parents and no publicly held corporation holds 10% or more of its stock.

Respondent Louisiana Wholesale Drug Company, Inc. certifies that Louisiana Wholesale Drug Company, Inc. has no corporate parents, and no publicly held corporation holds 10% or more of its stock.

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COUNTER-STATEMENT OF THE CASE

"Federal courts are courts of limited jurisdiction,"[1] and the Federal Circuit's jurisdiction is more limited still. In *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800 (1988), the Supreme Court imported the test for cases "arising under" federal law[2] to aid in defining the ambit of cases that could be heard by the Federal Circuit. Thus, the Federal Circuit was limited to appeals only in cases where patent law is necessary for a plaintiff to make out a right to relief. If a plaintiff asserts even one alternate non-patent theory supporting its claims, the case may not be heard by the Federal Circuit, even if issues of patent law are present.

The decision by the Second Circuit refusing to transfer this antitrust case to the Federal Circuit holds true to *Christianson*. Plaintiffs Meijer, Inc., Meijer Distribution, Inc., Rochester Drug Co-operative, Inc., and Louisiana Wholesale Drug Co., Inc. ("Plaintiffs") are drug wholesalers and retailers who directly purchased the brand name prescription drug DDAVP (desmopressin acetate) from Defendants Ferring, B.V., Ferring Pharmaceuticals, Inc. ("Ferring") and Aventis Pharmaceuticals, Inc. ("Aventis").[3] Plaintiffs brought a single claim: for

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[1] *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994).

[2] *See* 28 U.S.C. § 1331.

[3] This term shall also refer to Aventis's corporate predecessors.

monopolization under the Sherman Act, 15 U.S.C. § 2. Petitioners' Appendix ("App.") 104a-107a. As set forth in Plaintiffs' Complaint,[4] Defendants engaged in a multi-faceted scheme to unlawfully maintain their monopoly over desmopressin acetate. Defendants' actions included filing a sham citizen petition with the FDA to delay regulatory approval for a prospective generic rival, causing direct purchasers to be overcharged.

In keeping with *Christianson*, the Second Circuit declined transfer. Because the sham citizen petition theory alone, if proven, would sustain a successful claim for monopolization and entitle Plaintiffs to relief without invoking patent law, the Federal Circuit lacks jurisdiction.[5]

Defendants claim that the Second Circuit, rather than follow *Christianson*, should have concentrated on sections of the Complaint which touch on patent issues and surrendered the case to the Federal Circuit. The Complaint does allege that Defendants employed *additional* anticompetitive means to block rivals, including defrauding the United States Patent and Trademark Office ("PTO")

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[4] Consolidated Amended Class Action Complaint, March 31, 2006 ("Complaint"), *reprinted in* Petitioners' Appendix at 58a-116a ("App.").

[5] Defendants do not dispute that monopolization via a sham citizen petition does not rely upon patent law.

to obtain patent no. 5,407,398 ("the '398 patent");[6] making a fraudulent listing in the "Orange Book" maintained by the Food and Drug Administration ("FDA"); and engaging in sham litigation. Defendants harp on these additional allegations to convert a claim that *touches on* patent law theories into a claim that *arises under* patent law.

However, as the Second Circuit observed, *Christianson* focuses on "claims, not theories," App. 15a (quoting *Christianson*, 486 U.S. at 811), and the presence of these additional, alternative theories for relief does not alter the analysis. *See Christianson*, 486 U.S. at 812 (Federal Circuit lacks jurisdiction where plaintiff's "well-pleaded complaint" states "reasons completely unrelated to the provisions and purposes of federal patent law why [plaintiffs] may or may not be entitled to the relief they seek under their monopolization claim.") (citations, internal quotes and original alterations omitted). If Plaintiffs were to succeed on their sham citizen petition theory, both Defendants could be held liable for treble damages under the antitrust laws – and no issue of patent law would need to be addressed or resolved.[7]

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[6] *See Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).

[7] Defendants also propose a new rule – that a plaintiff must show entitlement to "all" relief it seeks without relying on patent law, but this standard finds support neither in *Christianson* nor Defendants' other citations.

Therefore, the Second Circuit "not only may, but must"[8] retain jurisdiction.

Defendants also attempt to manufacture a circuit split, but they cite cases far removed from the one at bar. Indeed, a proper reading of those cases shows they accord with those of the Second Circuit.

Nor is the Federal Circuit's guidance needed here. Defendants have already been to the Federal Circuit once, and it has already held that the only patent potentially at issue here was unenforceable and found evidence that Defendants "*deliberately concealed*" "*pivotal*" information from the PTO. *Ferring, B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1189, 1193 (Fed. Cir. 2006) ("*Ferring II*").

Moreover, although Defendants discuss the question of whether direct purchasers should have standing to bring an antitrust claim, they have not sought certiorari on that point. Regardless, *antitrust standing* is quintessentially a question of *antitrust* law, which regional circuits are competent to address and for which Federal Circuit guidance is unnecessary.

For these reasons, the petition for certiorari should be denied.

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[8] *Pratt v. Paris Gas Light & Coke Co.*, 168 U.S. 255, 260 (1897).

FACTUAL BACKGROUND

I. Regulatory Overview

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et. seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act" or "Hatch-Waxman"), and the Medicare Prescription Drug, Improvement and Modernization Act of 2003, *codified at* 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e), establish procedures for obtaining approval to market pharmaceutical products in the United States. App. 66a.

A manufacturer seeking to market a new drug must file with the FDA a New Drug Application ("NDA") demonstrating the safety and efficacy of the product. *Id.* (citing 21 U.S.C. § 355(b)). Such new drugs may be covered by a patent. The NDA filer must identify any patent that claims the drug for which FDA approval is being sought, or that claims a method of using the drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug. App. 66a-67a.

The FDA maintains a list of approved "Reference Listed Drugs" in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." App. 67a. Once the FDA approves an NDA, the drug may be listed in the Orange Book, along with any patent that: (1) claims the approved

drug; and (2) with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engages in the manufacture, use, or sale of the drug. *Id.* (citing 21 U.S.C. § 355(j)(7)(A)(iii)).

II. Generic Drugs

The Hatch-Waxman Act was passed in 1984 to speed the entry of less expensive generic drugs to the market. App. 69a. *See also In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991). Generic drugs are virtually identical to their brand-name counterparts, but are typically much less expensive. App. 68a-69a.

Hatch-Waxman permits a drug company to file an "Abbreviated New Drug Application" ("ANDA") that may rely on safety and efficacy data previously submitted by the NDA filer regarding a particular drug. App. 69a.

However, brand drug companies have exploited certain features of Hatch-Waxman to wrongfully block and delay generic competition and thereby inflict massive overcharges on purchasers. If a patent is listed in the Orange Book for a particular drug, an ANDA filer, seeking to market a generic version before the patent has expired, must certify that each listed patent is either invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification"). App. 70a-71a (citing 21 U.S.C. § 355(j)(2)(A)(vii)). A Paragraph IV certification allows the patent holder,

by filing a patent infringement suit within 45 days, to delay FDA approval of the ANDA automatically for up to 30 months. App. 71a. The patent holder can obtain this delay without any showing that its patent is valid or infringed by the proposed generic. App. 72a. Because generic drugs are significantly cheaper than brand drugs, and typically are substituted rapidly for the brand, brand name drug companies have very strong financial incentives to delay generic competition by any means, including by filing patent infringement suits regardless of their merits. App. 72a-73a.

In addition, branded drug companies can abuse the citizen petition process before the FDA by asking the agency to investigate the safety and efficacy of a proposed generic drug. 21 C.F.R. § 10.30. Merely filing a petition can cause a time-consuming and often unnecessary review, substantially delaying approval of a generic's ANDA. App. 92a. Branded drug companies thus have an incentive to lodge such petitions regardless of their merit. The FDA's chief counsel has noted repeated abuses of the citizen petition process to delay generic competition. App. 92a-93a.

III. Defendants' Scheme to Monopolize

DDAVP is the brand name of the prescription drug desmopressin acetate, an anti-diuretic used to manage diabetes insipidus, excessive urination and thirst, and bed wetting. App. 59a. In 1969-70, Ferring obtained two patents related to this drug:

patent no. 3,454,549 ("the '549 Patent") and patent no. 3,497,491 ("the '491 patent"). App. 75a.

Respondents sold tens of millions of dollars of desmopressin products during the 1980s. However, Defendants foresaw that, once the '549 and '491 patents expired, that cash stream would dry up as less expensive generics captured the market. App. 76a. Defendants undertook a multifarious scheme to block generic competition and preserve and extend their monopoly on desmopressin products. *Id.*

A. Fraud on the PTO

On December 17, 1985, Ferring applied for a patent claiming a tablet form of desmopressin acetate, absorbed through the stomach and intestines (the "'398 Application"). App. 78a.

The PTO was reluctant to issue the patent, however, and the application was rebuffed multiple times. The PTO examiner assigned to the '398 Application was concerned that the '491 patent's disclosure of "peroral" application suggested oral administration for absorption via the stomach, since "peroral" means "through the mouth." App. 79a. The examiner knew that Ferring had an economic incentive to seek further patent protection and accordingly, specifically requested evidence from a "non-inventor" to support the claim that the '398 was not obvious in light of prior art. App. 79a-80a. In addition, the PTO's Manual of Patent Examining Procedure also stated that a declarant's interest

warranted close scrutiny. App. 84a. Thus, from the very outset, Ferring was on notice of the PTO's concern about declarants' bias.

Nevertheless, over the course of the next four years while the '398 patent application was prosecuted before the PTO, Ferring submitted a series of declarations to convince the PTO to issue a patent, while repeatedly concealing that the declarants had financial and other ties to Ferring. App. 80a-84a.

On November 21, 1990, Ferring submitted a final set of declarations to the PTO, with each declarant opining why, in his professional opinion, the '398 Application was not obvious in light of the prior art. App. 82a. These same declarations, however, were riddled with fraudulent omissions. They failed to disclose that four of the declarants were former Ferring employees or had received research funds from the company; that two of the declarations supposedly being submitted by alleged "non-inventors" were drafted with the inventor's aid; and that one declarant had *no* expertise in DDAVP tablets and could not recall having done any research on drug delivery systems or on absorption of peptides in the gastrointestinal tract – two issues central to evaluating whether the '398 Application was obvious in light of prior art. App. 82a-83a.

The patent examiners were not, and could not have been, aware of the declarants' multiple, undisclosed ties to Ferring. App. 82a.

On April 8, 1991, the PTO – after repeatedly rejecting the '398 Application and only after receiving the final set of fraudulent declarations – reversed course and allowed the '398 patent to issue. App. 84a.

B. The Sham Orange Book Listing

Although the '398 patent had been obtained by fraud, Defendants amended the listing for DDAVP in the Orange Book to include the patent. App. 84a-86a. Defendants knew that by listing the patent, they could block any potential generic competitor filing a Paragraph IV certification for 30 months merely by filing suit. App. 70a-73a, 85a-87a.

After receiving FDA approval, DDAVP tablets were introduced to the market. Sales for DDAVP tablets grew from $78 million in 2000, to $125 million in 2002, to $180 million in 2004. App. 86a.

C. The Sham Litigation

Two potential competitors – Barr Laboratories, Inc. ("Barr") and Teva Pharmaceuticals USA, Inc. ("Teva") – sought to market generic versions of DDAVP. Each filed an ANDA and a Paragraph IV certification certifying that the '398 patent was either invalid or would not be infringed by its respective generic formulations. App. 87a, 91a.

Despite Barr's certification, and despite the fact that the '398 patent had been obtained by fraud,

Ferring and Aventis sued Barr and alleged infringement of the '398 patent. App. 88a-89a. Ferring also sued Teva. App. 91a. These suits triggered the 30-month stay provisions of Hatch-Waxman. App. 71a-73a, 88a, 91a.

In April 2004, Barr moved for summary judgment on the issue of inequitable conduct. The district court held on Feb. 7, 2005, that the '398 patent was unenforceable due to "***clear and convincing evidence***" of "***deceit... practiced over a long period of time by more than one person***" which "***appears to have been outcome determinative.***" App. 88a-89a (emphases added) (*quoting Ferring B.V. v. Barr Labs., Inc.*, No. 02 Civ. 9851, 2005 WL 437981, *10 (S.D.N.Y. Feb. 7, 2005) ("*Ferring I*")). The court found that, "the PTO ***must have relied substantially*** on these declarations, as there ***is no alternative explanation*** offered for the Board's final allowance of the claims after several prior rejections by the PTO." App. 89a (emphases added).[9]

The Court of Appeals for the Federal Circuit affirmed on February 15, 2006. App. 89a. In a strongly-worded opinion, the Federal Circuit found that: (a) the failure to disclose the past relationships between the declarants and Ferring was "*highly material* as a matter of law" because the PTO was specifically concerned about bias and the objectivity

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[9] *See also Ferring I*, 2005 WL 437981, at *9-10.

of those trying to distinguish prior art, and therefore had specifically requested "non-inventor" affidavits;[10] (b) the omissions were made with an intent to deceive;[11] and (c) the repeated omissions over a prolonged period of time "support[] a conclusion that the past relationships ***were deliberately concealed.***"[12]

> The Federal Circuit further found that:
>
> [T]he second set of declarations... plagued with even more undisclosed affiliations than the first set, *was absolutely critical in overcoming the Board's obviousness rejection.*
>
> * * *
>
> *Not only were these declarations pivotal, they were essentially opinions that were supported largely by the declarants' own scientific expertise and little else.*

Id. at 1189 (emphases added).

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[10] *Ferring II*, 437 F.3d at 1190 (emphasis added).

[11] *Id.* at 1190-93.

[12] *Id.* at 1193 (emphasis added).

D. The Sham Citizen Petition

As part of Defendants' over-arching scheme, on February 2, 2004, Ferring filed a sham citizen petition with the FDA pursuant to 21 C.F.R. § 10.30, asking the agency to require Barr to submit additional tests before its generic product could be approved. App. 93a-94a. Although Ferring certified that it had included "all information... known to the petitioner [] unfavorable to the petition," App. 95a, it failed to disclose a study sponsored by Aventis (the "Aventis Study") that directly undermined the petition. App. 96a.

Ferring knew or should have known of the Aventis Study, but did not disclose it; and Aventis knew or should have known that the petition had omitted the Aventis Study, but did nothing to correct it. App. 96a.

Ferring I was issued on February 7, 2005. The Court stated that the citizen petition – then still pending – had been "motivated by a desire to keep out competition for as long as possible." 2005 WL 437981, at *17. Despite the Court's conclusions concerning the "fraudulent omissions" and other blatant misconduct used to obtain the '398 patent, Aventis and Ferring allowed the sham petition to remain on file. The '398 patent had been held unenforceable, but the sham petition blocked Barr's generic product. App. 97a-100a.

On July 1, 2005, the FDA rejected the citizen petition as lacking "***any basis***" and explicitly relied on the Aventis Study. The same day, Barr received final FDA approval, and launched its cheaper generic DDAVP tablets. App. 100a. After the expiration of Barr's 180-day exclusivity period, Teva and another generic competitor, Apotex Corp., also came to market. *Id.*

IV. Procedural History

Plaintiffs brought suit as direct purchasers of DDAVP tablets. They filed their amended complaint on March 31, 2006, asserting a single claim for monopolization in violation of 15 U.S.C. § 2. App. 104a-107a.

Plaintiffs requested relief in the form of overcharges pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15. App. 108a. Plaintiffs alleged that but for Defendants' conduct, generic competition would have occurred earlier than it did. App. 102a-103a. However, due to Defendants' conduct, generic competition did not begin until July 1, 2005 – the date the citizen petition was denied and Barr received final FDA approval.[13]

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[13] Defendants and Amici make it sound as though the bulk of the alleged injuries occurred before the patent was ruled unenforceable (or the citizen petition filed). *E.g.*, Petition at 16. However, Plaintiffs only allege that generic entry would have occurred earlier than it did. App. 102a. This allegation is

Defendants moved to dismiss, arguing that Plaintiffs, despite their undisputed status as direct purchasers, lacked standing to bring this antitrust case. Defendants argued that no purchasers, direct or otherwise, should have standing to bring a federal antitrust action for overcharges resulting from fraud on the PTO. Instead, argued Defendants, only alleged injured competitors – who would have separate and different claims for lost sales and profits – should have such antitrust standing. Aventis separately argued that it was not sufficiently implicated in any wrongdoing, even though it had, for example, participated in planning the citizen petition. The district court dismissed, also deciding (without affording Plaintiffs any notice or opportunity to be heard) that Plaintiffs had failed to state a claim. App. 35a-55a.

Plaintiffs appealed to the Court of Appeals for the Second Circuit. Defendants moved to transfer the appeal to the Federal Circuit.

The Court of Appeals for the Second Circuit denied the motion to transfer, and vacated and remanded, finding that Plaintiffs had satisfied the standards for antitrust standing. *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 688-92 (2d Cir. 2009), *reprinted in* App. 1a-34a. The court emphasized that a *Walker Process* theory sounds in antitrust. App. 22a-23a. Further, the

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sufficient to allege antitrust injury.

court observed that "*Walker Process* does not necessarily suggest [] a limit" on standing, but rather calls for the patentee to "answer" for its wrongdoing "to *those injured by any monopolistic action*[.]" App. 23a. (emphasis in original) (quoting *Walker Process*, 382 U.S. at 176).

The Second Circuit also found that it, rather than the Federal Circuit, had jurisdiction. App. 8a-16a. The court applied the *Christianson* test, observing that if "there are reasons completely unrelated to the provisions and purposes of federal patent law why [Plaintiffs] may or may not be entitled to the relief they seek under their monopolization claim," then "the claim does not arise under federal patent law" and the Federal Circuit lacks jurisdiction. App. 9a (citing *Christianson*, 486 U.S. at 812).

The court also found that Plaintiffs' fourth theory of liability – the sham citizen petition filed with the FDA – "does not turn on a substantial question of patent law." App. 11a. Plaintiffs could sustain their prima facie case for monopolization by demonstrating that Defendants' sham citizen petition was not entitled to *Noerr*[14] immunity because it was objectively baseless. App. 11a-13a. Further, Plaintiffs were injured by the citizen petition because it delayed the availability of generic

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[14] *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961) ("*Noerr*").

DDAVP. Indeed, for a substantial period of time, the patent had already been ruled unenforceable, removing any potential patent-related defense. 14a-16a.

The court then sustained each of Plaintiffs' theories under Rule 12, upheld Plaintiffs' allegations against Aventis, and therefore did not reach Plaintiffs' due process argument. App. 25a-34a.

Defendants have now petitioned for certiorari, seeking review only of whether the appeal should have been transferred to the Federal Circuit.

ARGUMENT

I. The Second Circuit Faithfully Followed The Standard Announced In *Christianson*

A. *Christianson* Forecloses Federal Circuit Jurisdiction For Well-Pleaded Complaints Which Do Not Depend On Patent Law

1. The Court of Appeals faithfully followed this Court's decision in *Christianson*. Plaintiffs' sole claim for monopolization was supportable without necessarily depending on patent law because Plaintiffs would be entitled to relief by virtue of their citizen petition theory alone. If the Complaint were limited to the sham citizen petition theory, Plaintiffs could still prove Defendants' liability under the Sherman Act and obtain damages under the

Clayton Act, all without having to resolve any issue of patent law. In essence, Defendants argue that this Court should abandon the well-pleaded complaint rule long used as the benchmark for Federal Circuit jurisdiction.

As a general matter, the Second Circuit has jurisdiction over final decisions from district courts within its aegis. *See* 28 U.S.C. §§ 1291, 1294.

In contrast, the Federal Circuit's jurisdiction is strictly limited, extending to cases where district court jurisdiction is based on 28 U.S.C. § 1338. 28 U.S.C. §1295(a)(1). Section 1338, in turn, grants jurisdiction for cases "arising under any Act of Congress relating to patents[.]" 28 U.S.C. § 1338(a).[15] The "arising under" language of § 1338 is construed akin to the "arising under" language which forms the basis for federal question jurisdiction, 28 U.S.C. § 1331. Thus, jurisdiction under § 1338 extends:

> only to those cases in which a well-pleaded complaint establishes either that [1] federal patent law creates the cause of action or [2] that the plaintiff's

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[15] The Federal Circuit has observed that Congress intended it to apply the long-standing "canon of construction" to "strictly construe [its] jurisdiction." *Christianson v. Colt Indus. Operating Corp.*, 822 F.2d 1544, 1556 (Fed. Cir. 1987) (quoting S. Rep. No. 275, 18-19, *reprinted in* 1982 U.S.C.C.A.N. 11, 28-29), *vacated on other grounds*, 486 U.S. 800 (1988).

> right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims.

Christianson, 486 U.S. at 809. However, "[n]ot all cases involving a patent-law claim fall within the Federal Circuit's jurisdiction." *Holmes Group, Inc. v. Vornado Air Circulation Sys. Inc.*, 535 U.S. 826, 834 (2002). It is not enough that a complaint may reference theories which incorporate patent law:

> If on the face of a well pleaded complaint there are reasons completely unrelated to the provisions and purposes of the patent laws why the plaintiff may or may not be entitled to the relief it seeks, then the claim does not "arise under" those laws.

Christianson, 486 U.S. at 810 (internal quotes and original alternations omitted). "Thus, a claim supported by alternative theories in the complaint may not form the basis for § 1338(a) jurisdiction unless patent law is essential to each of those theories." *Id.*

2. The decision *sub judice* fully comports with *Christianson.* The Second Circuit found, and Defendants agree (Petition for a Writ of Certiorari ("Petition") at 11), that "because the plaintiffs have

filed an antitrust suit, patent law does not create the cause of action." App. 9a.

Thus, to meet their burden of establishing Federal Circuit jurisdiction, Defendants had to meet the second test under *Christianson* – that "[P]laintiff[s'] right to relief necessarily depends on resolution of a substantial question of federal patent law." 486 U.S. at 809.

Here, Plaintiffs' right to relief depends on showing a violation of Section 2 of the Sherman Act, *viz.*, (1) the possession of monopoly power; and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident, *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966), and antitrust injury. *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 114 & n.9 (1969).

The Court of Appeals found that Plaintiffs' sham citizen petition theory did not depend on patent law. App. 11a-13a. Although petitioning a government agency may ordinarily be protected, if such acts are "a... sham to cover what is... nothing more than an attempt to interfere directly with the business relationships of a competitor[, then] the application of the Sherman Act would be justified." App. 12a (alterations in original) (quoting *Noerr*, 365 U.S. at 144). Because the sham citizen petition theory supports a claim under Section 2 without

necessitating patent law, Federal Circuit jurisdiction is unavailable.

Although Plaintiffs may have had *additional* theories which involve patent law, the existence of one theory that is independent of patent law meant that the Second Circuit correctly retained jurisdiction, and correctly denied Defendants' motion to transfer.

B. Defendants' Proposed New Rules Contradict *Christianson*

1. Defendants mistakenly believe the Second Circuit erred because, in their view, the "'core' of [P]laintiffs' claim" is Defendants' fraudulent procurement and enforcement of their patent. Petition at 13. Defendants seek to supplant the *Christianson* test by allowing defendants to pick which parts of the complaint they view as more "important" and site jurisdiction accordingly.

It is not for Defendants to decide which of Plaintiffs' theories are more important. Plaintiffs are "the master[s] of the complaint"[16] and Defendants cannot recast Plaintiffs' allegations for them.[17]

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[16] *Holmes*, 535 U.S. at 831.

[17] *Tennessee v. Union & Planters' Bank*, 152 U.S. 454, 464 (1894) ("a suggestion of one party, that the other will or may set up a claim under the Constitution or laws of the United States, does not make the suit one arising under that Constitution or

In focusing on the allegations of fraudulent patent procurement, Defendants mistake them for a separate claim. These allegations describe merely one of several means – one theory among several – by which Defendants obtained and maintained monopoly power. While some of Defendants' misdeeds involved abuses of patent rights, others, like the citizen petition, did not. This case thus stands in stark contrast to the cases Defendants cite (Petition at 13 n.4), which involved claims necessarily dependent on patent law,[18] or sought relief available only under patent law.[19]

Amici also suggest using Rule 12 to distinguish between claims and theories (Brief of Intellectual Property Owners Association as *Amicus Curiae* in Support of Petitioners at 12-13), but Defendants could not win dismissal of Plaintiffs' monopolization claim even if Plaintiffs' patent-related allegations were found wanting. Indeed,

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those laws."). Nor can Defendants recharacterize the Complaint by picking out language from the Court of Appeals' decision. Cf. Petition at 17 n.5.

[18] *E.g., Hunter-Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1329 (Fed. Cir. 1998) (claim arose under patent law because "a required element ... necessarily depends on a question of federal patent law"), *overruled on other grounds, Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356 (Fed. Cir. 1999).

[19] *E.g., Jacobsen v. Katzer*, 535 F.3d 1373, 1377 (Fed. Cir. 2008) (complaint contained claims for declaratory judgment that patent was not infringed or was invalid).

Defendants' original joint motion to dismiss challenged only Plaintiffs' standing to assert *Walker Process* fraud. Had Defendants prevailed (and had the District Court not improperly exceeded that motion and dismissed the whole case), Plaintiffs' claim for relief would have survived.

Indeed, in belittling the citizen petition, Defendants minimize the public harm wreaked by the use of such petitions to delay the entry of cost-saving generics. The concern was serious, as attested to by both the Federal Trade Commission and the FDA itself. App. 92a-93a. Such petitions exemplify Judge Bork's concern that "[t]he modern profusion of... governmental authorities offers almost limitless possibilities for abuse[.]" Robert H. Bork, THE ANTITRUST PARADOX 347 (1993).

Moreover, the relief Plaintiffs seek – a declaration that "Defendants' actions... to be a violation of Section 2 of the Sherman Act" and overcharge damages (App. 107a-108a) – can be granted whether the monopolistic conduct is the sham citizen petition alone or Defendants' fraud on the PTO.[20] The Second Circuit thus kept the focus on

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[20] Defendants excerpt Plaintiffs' Complaint out of context (Petition at 15-16) to give the appearance of a patent claim. In addition to alleging four theories of monopolization, Plaintiffs also alleged an "overarching scheme" by Defendants. App. 74a. As with most schemes, Defendants' means overlapped to a common end: "to protect their monopoly." App. 59a. This is akin to *Christianson*'s complained-of "course of conduct to

"claims, not theories," and just because some particular theory "might be governed by federal patent law does not mean that the entire monopolization claim 'arises under' patent law." App. 15a (quoting *Christianson*, 486 U.S. at 811 (internal citations omitted)).

The Second Circuit's analysis thus accords with *Christianson*. There, the plaintiff alleged that various actions were in violation of the antitrust and other laws. *Id.* at 805-06. The defendant had appealed to the Federal Circuit, claiming jurisdiction by focusing on one theory outlined in the complaint said to depend on patent law. *See id.* at 806, 811. The Supreme Court, however, noted that the theory the defendant emphasized was "only one of several", and that plaintiffs could also prevail under other theories. *Id.* at 811. Like here, the presence in the complaint of an "alternative, non-patent theory

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illegally extend its monopoly", which was also supported by separate theories and various separate and interlocking actions, some of which raised patent questions while others did not. *Christianson*, 486 U.S. at 810. Defendants also misleadingly suggest that Plaintiffs seek a judgment "declaring *all* of defendants' alleged actions ... to be unlawful." (Petition at 15-16) (emphasis in original). To prevail, Plaintiffs only need *some* of Defendants' "actions" to be declared unlawful. The citizen petition itself involved many such "actions," including, *inter alia*, planning and submitting the petition, the continued concealment of Defendants' own study that undermined their petition, and its continued prosecution. App. 93a-96a.

compels the conclusion that the [antitrust] claim does not 'arise under' patent law[.]" *Id.* at 813.

2. Defendants also claim the Second Circuit erred because, in their view, damages predating the loss of their patent case depend on patent law. The Second Circuit correctly observed that "this fact lacks jurisdictional significance." App. 15a. Plaintiffs seek a declaration that Defendants violated 15 U.S.C. § 2, and Plaintiffs' suffered overcharges. A claim under Section 2 is stated simply by proving a violation and the fact of injury. Defendants' point merely goes to the quantum of damages. So long as Plaintiffs make out a case for some damages, they have stated a claim for relief.[21]

Defendants thus seek to create a new rule requiring every penny of alleged damages to be independent of patent law, or else the case must be transferred to the Federal Circuit. *Christianson* nowhere imposes such a requirement. Indeed, *Christianson* does not discuss damages at all, simply the gravamen of liability. *See, e.g., Christianson*, 486 U.S. at 811 (identifying elements for liability under Sherman Act § 2). Defendants cherry-pick two words in *Christianson*: "overall success,"[22] and take them to mean "all" relief. But the full quote

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[21] To state a claim under the Sherman Act, Plaintiffs need only show *some* antitrust injury, the exact quantity is a question of damages. *See Zenith Radio*, 395 U.S. at 114 & n.9.

[22] *Christianson*, 486 U.S. at 810.

undermines Defendants' gloss: "The patent-law issue, while arguably necessary to at least one theory under each claim, is not necessary to the overall success of either claim."[23] In other words, patent law was not necessary to the success of either claim "viewed as a whole."[24]

Such a rule fully comports with the basis for the narrow jurisdiction of the Federal Circuit, which was empowered to hear only cases which present substantial questions of patent law. Expanding that jurisdiction, as Defendants would have it, would destroy the careful balance struck by Congress. *See* S. Rep. No. 97-275, at 4 (1982), *reprinted in* 1982 U.S.C.C.A.N. 11, 14 ("it is not the committee's judgment that broader subject matter jurisdiction is intended for this court").

That danger is evident here, where Plaintiffs' injury can be attributed to the citizen petition alone without relying on any patent law, because the citizen petition was a material cause of Plaintiffs' injury.[25] That is, for the period following the ruling of the unenforceability of the '398 patent, *no patent*

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[23] *Id.*

[24] MERRIAM-WEBSTER'S COLLEGIATE DICTIONARY 883 (11th ed. 2003) ("overall").

[25] *Zenith Radio*, 395 U.S. at 114 n.9 ("It is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury").

issues existed.[26] Even beforehand, the sham citizen petition was a material cause of Plaintiffs' injuries.[27]

II. There Is No Circuit Split

Defendants next claim that the decision below conflicts with decisions of the Federal Circuit and the Seventh Circuit. That is incorrect. These courts are all in accord. Indeed, all courts, including the Federal Circuit, recognize that a claim supported by

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[26] Defendants also claimed below that to prove an "intent to monopolize" via the citizen petition, Plaintiffs must show Defendants believed that the patent was likely to be ruled unenforceable, which they claim involves patent law. The Second Circuit correctly noted that Defendants left the sham petition on file after losing the patent case, exposing their intentions. App. 14a. Moreover, there is no requirement to prove an intent to monopolize in the sense Defendants suggest, for "no monopolist monopolizes unconscious of what he is doing." *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 602 n.28 (1985). In any event, proof that Defendants subjectively doubted that their patent alone would stop generic competition would not necessarily implicate substantive patent law, merely Defendants' state of mind, which could be proven circumstantially, including through their very act of filing the sham citizen petition.

[27] Defendants point to the definition of the proposed class which includes purchasers to the beginning of the statutory period in 2001 (Petition at 16), but this merely recites those who may be members of the class. The class is defined as all direct purchasers who were injured by a delay in generic entry – precisely what the citizen petition accomplished.

even a single non-patent theory does not arise under patent law.[28]

1. First, Defendants cite to *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008). There, the Second Circuit had transferred a case brought by indirect purchasers to the Federal Circuit. In doing so, however, the Second Circuit distinguished between the direct purchasers (who had raised a single claim based on multiple theories and therefore were not transferred), and the indirect purchasers, who had amended their complaint to add an additional state law claim of monopolization, supported solely through allegations of *Walker Process* fraud. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, Nos. 05-2851, 05-2852, 05-2863 (2d Cir. Nov. 7, 2007) (Respondents' Appendix 2a); *see also Arkansas Carpenters Health and Welfare Fund v. Bayer AG*, No. 05-2851-CV(L), 05-2852-CV(CON)), __ F.3d __, 2010 WL 1710683, *3 n.10 (2d Cir. Apr. 29, 2010).

After receiving the indirects' appeal, the Federal Circuit in *Ciprofloxacin* agreed that the indirects' state-law claim for monopolization, based on *Walker Process* (and nothing else), gave it jurisdiction. 544 F.3d at 1330 n.8. It did not hold, as Defendants suggest, that the mere presence of

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[28] *See, e.g., Clearplay, Inc. v. Abecassis*, 602 F.3d 1364, 1367-68 (Fed. Cir. 2010); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 200 (2d Cir. 2006).

Walker Process allegations creates jurisdiction. Two circuits at opposite ends of the same transfer can hardly be said to be in conflict.

2. Defendants next cite the decisions in *U.S. Valves, Inc. v. Dray*, 190 F.3d 811 (7th Cir. 1999), *upon transfer*, 212 F.3d 1368 (Fed. Cir. 2000), but have the teachings of those cases backward. There, the plaintiff could establish the defendant's breach of contract only by proving patent infringement. The issue of infringement was inextricably tied to plaintiff's ability to prove liability and *all* of the relief it sought. That is not the case here at all.

U.S. Valves and Dray contested payments due under a patent license agreement between them. Dray had patented an "internal piston valve" and had granted an exclusive license to U.S. Valves. 190 F.3d at 812. However, Dray then began selling valves on his own, both the internal piston valves and another type, sliding ring valves. *Id.* U.S. Valves sued for breach of the patent license, claiming that *both types of valves* which Dray sold had infringed the licensed patents. *Id.* Dray conceded that he had sold some internal piston rings covered by the patents, and the trial court awarded damages accordingly. *Id.*

U.S. Valves appealed to the Seventh Circuit, and Dray moved for transfer. The Seventh Circuit held that U.S. Valves' claim required "examin[ing] the patent and determin[ing] which valves are

covered and whether the patent was infringed." *Id.* at 814. The only way to determine whether there was a breach of contract *at all* vis-à-vis the sliding ring valves was relying on patent law. For the other type of valves, infringement was conceded (and if it had not been, patent law would have been a necessarily component there as well). Thus, the appeal was transferred to the Federal Circuit.

Upon transfer, the Federal Circuit reached the same conclusion. 212 F.3d at 1372.

Defendants portray these companion cases as if the jurisdictional decision rested on the determination that a "*portion* of U.S. Valves' infringement claim deal[t] with Dray's sale of sliding ring valves[.]" Petition at 23 (emphasis in original).

Not so. *No* damages were available to U.S. Valves without invoking patent law. The allegations of breach in U.S. Valves' complaint – with respect to *both* types of valves – required patent law because one needed to determine if any valves sold had infringed. The court focused on the sliding ring valves because they were the only products whose infringement remained in question. Dray had conceded infringement for the other valves, which was the basis for the district court's decision. But that concession was of no jurisdictional significance. A well-pleaded complaint seeking damages for the infringing internal piston valves would also rely on patent law. In other words, getting damages for both valves depended on patent law.

Dray is not in conflict with the Second Circuit, but in accord.

3. Finally, Defendants attempt to find a circuit split based on the Federal Circuit's decision in *Davis v. Brouse McDowell, L.P.A.*, 596 F.3d 1355 (Fed. Cir. 2010), but that decision merely applies *Christianson*. *See Davis*, 596 F.3d at 1359 (citing *Christianson*, 486 U.S. at 808-09). The court also found that a claim is an "aggregate of operative facts *giving rise to a right enforceable by a court*." *Davis*, 596 F.3d at 1360 (emphasis added). The court held the plaintiff there sought to lay claim to two different types of rights – each of which entailed distinct forms of injury.

In *Davis*, the plaintiff brought a malpractice suit against the defendant law firm, alleging what the Federal Circuit viewed as two distinct types of legal malpractice: (1) alleged missteps relating to her application for a U.S. patent and (2) failure to timely file a foreign patent application. *Id.* at 1360. The plaintiff was thus complaining of the loss of rights of two different characters: U.S. patent rights and foreign patent rights, and accordingly was seeking two types of relief: (1) lost in-U.S. patent royalties and (2) lost ex-U.S. patent royalties.[29] Establishing

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[29] Rights under foreign patents do not arise under U.S. patent law. Cf. *Voda v. Cordis Corp.*, 476 F.3d 887, 894 (Fed. Cir. 2007) (distinguishing jurisdictional basis for U.S. and foreign patent claims).

wrongful deprivation of a U.S. patent and its attendant royalties required proving "[t]he patentability of [plaintiff's] inventions" which was "controlled by U.S. patent law," *Davis*, 596 F.3d at 1362, and the Federal Circuit had jurisdiction.

In this light, *Davis* accords with the Second Circuit, which also examines the various *types* of rights and relief which the well-pleaded complaint seeks. Cf. *Broder v. Cablevision Sys. Corp.*, 418 F.3d 187, 194-95 (2d Cir. 2005) (finding plaintiff who sought relief, federal in character and which existed only under federal law, had stated a claim arising under federal law).

Unlike Davis, who sought to establish multiple rights in her complaint, Plaintiffs here seek relief of one character – a finding that Section 2 of the Sherman Act was violated and that Plaintiffs are entitled to antitrust damages. That an additional quantum of damages of the same character might be available by referencing patent law does not change that jurisdictional analysis. Nothing in *Davis* is to the contrary.

The more recent decision in *Clearplay, Inc. v. Abecassis*, dispels any doubt that the Federal Circuit, like the Second Circuit, recognizes the distinction between claims and theories, and that it lacks jurisdiction when the claims in the complaint can be supported by non-patent theories. 602 F.3d at 1368-69. Although there it was "*possible* that patent law issues could arise in the course of litigating any

one of [plaintiff's] claims, it is equally clear that none of those claims *necessarily* turns on an issue of patent law." *Id.* at 1368 (emphases added). It therefore lacked jurisdiction.

The court also rejected a contention, like that made by Defendants here, that the alleged centrality of patent issues warranted jurisdiction:

> While it may be true, in a holistic sense, that the dispute between these parties is patent-based, *the Supreme Court's decision in Christianson embraces a distinctly non-holistic approach to "arising under" jurisdiction.* It is not enough that patent law issues are in the air. Instead, *resolution of a patent law issue must be necessary to every theory of relief under at least one claim in the plaintiff's complaint. And that is not so in this case.*

Id. at 1369 (emphases added).

The Second Circuit and the Federal Circuit therefore agree: if patent law is not essential to any claim, the Federal Circuit has no jurisdiction, even if patent issues are prominent in the complaint. Thus, Defendants' effort to manufacture a circuit split is unavailing.[30]

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[30] The unanimity of recent appellate decisions on point belies

III. Concerns About Forum Shopping And The Uniformity Of Patent Law Do Not Justify Deviating From The Well-Pleaded Complaint Rule

A. The *Christianson* Rule Defines Federal Jurisdiction and Prevents Forum Shopping

Defendants next argue that *Christianson* should be disregarded on policy grounds because it makes it too difficult to haul plaintiffs to the Federal Circuit. (Petition at 17-19). They also argue that Congressional intent for uniformity in patent law will somehow be frustrated if all antitrust cases with patent elements are not sent to that court. (Petition at 27-29). However, Congress intended to grant the Federal Circuit only *limited* jurisdiction to aid nationwide uniformity in *patent* law. *See* S. Rep. No. 97-275 at 4, *reprinted in* 1982 U.S.C.C.A.N. at 14. Congress was particularly mindful of criticism that the Federal Circuit might inappropriately assert jurisdiction over cases under the antitrust laws. *See* Ronald S. Katz & Adam J. Safer, *Should One Patent*

Amicis' claim of doctrinal uncertainty. (Brief of the Biotechnology Industry Organization, et al. as *Amici Curiae* in Support of Petitioners, 12-13) ("BIO Brief"). Although they cite some old statements expressing such concern (including some pre-dating Congress's creation of the Federal Circuit), they cite no *recent* source claiming that courts or practitioners are befuddled.

Court Be Making Antitrust Laws for the Whole Country?, 69 ANTITRUST L.J. 687, 689-90 (2002).

The Supreme Court has heard and rejected Defendants' "uniformity of patent law" argument twice before. The defendants in *Christianson*, like Defendants here, contended that such concerns counseled sending that case to the Federal Circuit, despite the presence of a non-patent theory which sustained the complaint. This Court concluded, however, that Congress had determined the relevant focus for granting jurisdiction to the Federal Circuit was "by reference to the well-pleaded complaint, not the well-tried case." 486 U.S. at 813-14. The legislative history confirmed such a result. *Id.* (citing H.R. Rep. No. 97-312 at 41 (1981)). Thus, the jurisdictional mandates of § 1295(a)(1) and § 1338, and not Defendants' policy preferences, establish the means to ensure uniformity of patent law. *Id.*

Similarly, in *Holmes Group*, the Supreme Court rejected an attempt to expand Federal Circuit jurisdiction out of solicitude for uniformity of patent law. "Our task here is not to determine what would further Congress's goal of ensuring patent-law uniformity, but to determine what the words of the statute [§ 1295(a)(1)] must fairly be understood to mean." 535 U.S. at 833.

Likewise, the Federal Circuit has observed that the goal of "uniformity in the patent laws" is not hindered where "statutory limitations on the jurisdiction of this court and the federal district

courts, in conjunction with the well-pleaded complaint rule" mean that a case does not "arise under" patent law. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 599 F.3d 1277, 1285 (Fed. Cir. 2010). That may mean some patent questions will be addressed by regional circuits, but those courts are "perfectly competent... to determine patent 'questions' or 'issues' that may occasionally arise in cases within their jurisdiction." *Christianson*, 822 F.2d at 1552 n.10 (citations omitted).

Moreover, Federal Circuit guidance is unnecessary here. Defendants here have already obtained a ruling from the Federal Circuit that the '398 patent was unenforceable, finding evidence that Defendants "*deliberately concealed*" information which was "*pivotal*" and "*highly material as a matter of law*[.]" *Ferring II*, 437 F.3d at 1189, 1190, 1193 (emphases added).[31]

In addition, the Federal Circuit has held that a plaintiff may assert an antitrust claim invoking *Walker Process* even if it was not directly the subject of a patent enforcement action (and hence lacked

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[31] Thus, the extended discussion by Amici concerning regional circuit law on inequitable conduct is beside the point. BIO Brief at 16-21. Although Amici bemoan that regional circuits' patent law has been "frozen" since the 1980s (*Id.* at 19), regional circuits confronting patent issues can do precisely what the Second Circuit did here – look to Federal Circuit precedent. *See* App. 26a-30a (citing Federal Circuit precedent seven times).

standing for a patent claim). *Hydril Company LP v. Grant Prideco LP,* 474 F.3d 1344 (Fed. Cir. 2007).

Defendants raise the specter of artful pleading, but a plaintiff is not going to be able to circumvent Federal Circuit jurisdiction where such jurisdiction is mandated. Should a plaintiff bring a true patent-based claim (*e.g.*, seeking infringement damages or a declaration of inventorship), it cannot defeat jurisdiction by omitting an essential question of patent law. *Christianson*, at 809 n.3 (citation omitted). Thus, if some future plaintiff should engage in artful pleading, a court will simply read the necessary patent law question into the complaint.

By the same token, a plaintiff who has no good faith, non-patent related basis to allege monopolization cannot simply make something up.

Defendants here, however, did file the citizen petition. They may dispute it was a sham, but they cannot dispute they filed it, and that it was rejected as lacking any basis. Plaintiffs' claim for monopolization does not need patent law to survive. There is simply no reference to patent law which Plaintiffs were required to plead but omitted. Furthermore, Plaintiffs, "master[s] of [their] complaint[,]" are not required to bring patent claims, and "by eschewing claims based on [patent] law," are

entitled to have the cause heard outside the Federal Circuit. *Holmes Group*, 535 U.S. at 831.[32]

Plaintiffs can thus hardly be accused of forum shopping. Rather, they appealed their antitrust case to the regional court of general jurisdiction. That is what Congress intended them to do. Congress was in fact concerned that a plaintiff may do the reverse: joining a patent claim to "avail [itself] of the jurisdiction of the Federal Circuit in avoidance of the traditional jurisdiction and governing legal interpretations of a regional court of appeals." S. Rep. 97-275, at 20, *reprinted in* 1982 U.S.C.C.A.N. at 30.

B. Deciding Whether Plaintiffs Have Antitrust Standing Does Not Call for Guidance from the Federal Circuit

Though Defendants do not seek certiorari on the question, they claim that the issue of whether Plaintiffs have antitrust standing should have been decided in the first instance by the Federal Circuit (Petition at 19-21).

First, the nature of the question on appeal is irrelevant. Jurisdiction does not "rest on the subject

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[32] Amici cite to *City of Chicago v. International College of Surgeons*, but the plaintiff there unquestionably pled "a number of federal constitutional claims" arising under federal law. 522 U.S. 156, 160 (1997). That these were federal claims, not theories, was not even discussed.

matter of the judge's decision, but rather the well-pleaded complaint." *U.S. Valves*, 190 F.3d at 813; *see also Scherbatskoy v. Halliburton, Co.*, 125 F.3d 288, 291 (5th Cir. 1997).

Second, the question of whether Plaintiffs – direct purchasers who allege they have been overcharged – have antitrust standing to bring an antitrust claim, is a question of antitrust law, not patent law. The Federal Circuit itself has declared itself bound to follow the law of the regional circuit on whether a plaintiff has antitrust standing. *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1362 (Fed. Cir. 2004), *rev'd on other grounds*, 546 U.S. 394 (2006). Thus, purported concerns of uniformity of patent law are not even implicated. Here, the Second Circuit applied conventional antitrust standing analysis, and found that Plaintiffs had standing. App. 16a-25a.

The decision in *DDAVP* comports with basic antitrust principles. The direct purchasers seek to recover overcharges arising from Defendants' monopolistic conduct and pricing, and are thus efficient enforcers of the antitrust laws. App. 16a-20a. *See also Illinois Brick Co. v. Illinois*, 431 U.S. 720, 746 (1977) (observing that to promote efficiency, deterrence, and antitrust enforcement, direct purchasers were "elevat[ed]... to a preferred position as private attorneys general").

Defendants attempt to transform Plaintiffs' allegations into a patent claim, taking rules for

standing to initiate a challenge under *patent law* and improperly import those standards into *antitrust* standing analysis. Petition 19-21. But this conceives of *Walker Process* as a kind of patent claim: the very error which the Seventh Circuit made – and the Supreme Court reversed – in *Walker Process*.[33] And "*Walker Process* itself, of course, reflects a willingness to let antitrust liability impact the patent system." App. 22a. As Amici concede, a *Walker Process* theory "arises under [the] antitrust laws[.]" BIO Brief at 15. Therefore, the Second Circuit here properly refused to strip Plaintiffs of standing, for fear of "creating the potential 'to leave a significant antitrust violation undetected or unremedied.'" App. 23a (*quoting Associated General Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 542 (1983)).

Defendants claim that the Second Circuit's decision on standing – again, an aspect of the decision on which Defendants have not sought certiorari on – may "chill" patent rights (Petition 20). But the law condemns, rather than protects, conduct like Defendants'. "Patents obtained by fraud and used to maintain a monopoly [] undermine both the

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[33] *See Food Mach. & Chem. Corp. v. Walker Process Equip., Inc.*, 335 F.2d 315, 316 (7th Cir. 1964), *rev'd*, 382 U.S. 172 (1965). The Seventh Circuit had affirmed dismissal of the antitrust claims reasoning that the suit sought the cancellation of a patent, and standing to seek such relief was then restricted to the U.S. government. This Court reversed.

patent system and the 'important public interest in permitting full and free competition in the use of ideas which are in reality a part of the public domain.'" Brief for the United States and Federal Trade Commission as *Amici Curiae* Supporting Plaintiffs-Appellants at 15, *In re DDAVP Direct Purchaser Antitrust Litig.*, Appeal No. 06-5525 (2d Cir.), filed May 25, 2007 (quoting *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969)).

Nor can Defendants invoke an "interest in protecting patentees... to frustrate the assertion of rights conferred by the antitrust laws." App. 23a (quoting *Walker Process*, 382 U.S. at 176). Having wrongly delayed generic competition, Defendants should be held answerable like any other antitrust defendant, and not win special rights to be heard in their preferred forum.

CONCLUSION

For these reasons, the Petition for Certiorari should be denied.

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May 28, 2010

APPENDIX

APPENDIX A — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT FILED NOVEMBER 7, 2007

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 7th day of November, two thousand seven,

Present:

Hon. Roger J. Miner,
Hon. Rosemary S. Pooler,
Circuit Judges.[1]

05-2851-cv (L)
05-2852-cv (CON)
05-2863-cv (CON)

In re Ciprofloxacin Hydrochloride Antitrust Litigation.

Defendants-Appellees move to transfer to the United States Court of Appeals for the Federal Circuit these

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1. The Honorable Thomas J. Meskill, who was originally assigned to the panel, died before oral argument. The remaining two members of the panel, who are in agreement, decide this case in accordance with Second Circuit Local Rule 0.14(b).

three appeals. Upon due consideration, it is hereby ORDERED that the motion is GRANTED as to the appeal docketed under 05-2863-cv, which is TRANSFERRED to the Federal Circuit because the *Walker Process* claim in that case arises out of patent law. *See Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 807 (1988) (finding that a case "arises under" federal patent law if "a well-pleaded complaint establishes . . . that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims").

However, the motion is DENIED as to the appeals docketed under 05-2851-cv and 05-2852-cv because the claims therein rely on several theories, including alternative theories that do not require the determination of any substantial question of patent law. *See In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 199 (2d Cir. 2006) (finding that "even if one theory supporting a claim essentially turns on an issue arising under patent law, as long as there is at least one alternative theory supporting the claim that does not rely on patent law, there is no 'arising under' jurisdiction under 28 U.S.C. § 1338"); *see also Christianson*, 486 U.S. at 809 (finding that a case raising a patent law defense will not, for that reason alone, be said to "arise under" patent law, "even if the defense is anticipated in the complaint").

Thus, the appeal docketed under 05-2863-cv is transferred to the Federal Circuit, while the appeals docketed under 05-2851-cv and 05-2852-cv will remain consolidated in this Court.

FOR THE COURT:
Catherine O'Hagan Wolfe, Clerk

By: s/ Lucille Carr

Supreme Court, U.S.
FILED
JUN 3 - 2010
OFFICE OF THE CLERK

No. 09-1175

IN THE

Supreme Court of the United States

FERRING B.V., FERRING PHARMACEUTICALS, INC., and AVENTIS PHARMACEUTICALS, INC.,

Petitioners,

v.

MEIJER, INC., MEIJER DISTRIBUTION, INC., ROCHESTER DRUG CO-OPERATIVE, INC., and LOUISIANA WHOLESALE DRUG CO., INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

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STATEMENT PURSUANT TO RULE 29.6

Petitioners' corporate disclosure statement was set forth at page *ii* of the Petition for a Writ of Certiorari, and there are no amendments to that statement.

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Petitioners respectfully submit this reply brief in support of their petition for a writ of certiorari.

ARGUMENT

The Second Circuit held that even though disputed patent issues are "the linchpin" of plaintiffs' case, their case is not based "in whole or in part" on patent issues. This remarkable holding is contrary to *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800 (1988), it is irreconcilable with other circuit decisions, and it would thwart Congress' express goals in establishing the Federal Circuit.

Plaintiffs, reiterating the Second Circuit's analysis, misinterpret *Christianson*. They contend that if a plaintiff combines both patent and non-patent allegations into a single count, the allegations are necessarily "theories" not "claims," and that the Federal Circuit lacks jurisdiction even if the relief sought in the complaint cannot be obtained without resolution of patent issues. Under this rubric, a plaintiff's denomination of allegations as "theories" or "claims" will determine jurisdiction, even if allegations labeled as "alternative theories" are based on different conduct at different times causing different legal injuries.

But that is not what *Christianson* holds, and the Second Circuit rule would gut this Court's reasoning. The jurisdictional test in *Christianson* is based on the substance of a plaintiff's case, not nomenclature. Properly construed, *Christianson* focuses on whether the relief sought by plaintiffs requires patent issues to be resolved, not whether the patent allegations are labeled a "theory" or a "claim."

It is indisputable that the damages and injunctive relief actually sought by plaintiffs *require* the resolution of plaintiffs' patent allegations. Plaintiffs have not alleged the non-patent (citizen petition) conduct as an alternative "theory" of their antitrust claim, separate from the patent fraud and sham patent enforcement allegations. To the contrary, the complaint expressly asserts that the non-patent (citizen petition) allegation is just one aspect of an "overarching scheme" that consists primarily of alleged patent misconduct. Moreover, plaintiffs concede that the relief they seek arises from "Defendants' conduct as a whole," not from the citizen petition alone. Pet. App. 74a; *see* Opp. Br. at 13 (characterizing citizen petition as merely "part of Defendants' over-arching scheme"); *id.* at 32 (separate damages).

If the Second Circuit had followed *Christianson*, it would have concluded that the Federal Circuit has exclusive jurisdiction, regardless of whether plaintiffs' allegations are labeled "theories" or "claims." In order to retain jurisdiction of this appeal, the Second Circuit was compelled to re-write the *Christianson* test to change two key elements. First, the new Second Circuit rule accepts plaintiffs' characterization of their patent allegations as "theories," instead of making an independent assessment of whether they are necessary to plaintiffs' actual claims for relief. Second, it denies Federal Circuit jurisdiction if *any* non-patent theory advanced by plaintiffs can provide *any* relief — even if only a fraction of the relief actually sought in the complaint.

It is uncontested that disputed patent issues are the heart of this case. It is uncontested that the plaintiffs allege both *Walker Process* fraud and sham patent enforcement — claims that are indisputably subject to the exclusive jurisdiction of the Federal Circuit. Any rule holding that such an appeal is not based "in whole or in part" on patent law issues is clearly erroneous and fraught with mischief.

The ramifications of the decision below are of national importance. The decision undercuts the goals of Congress in creating the Federal Circuit: to reduce appellate forum shopping and to reduce the "widespread lack of uniformity" in patent law. Plaintiffs argue that Congressional policy cannot be a basis for disregarding this Court's opinions. They have it backwards.

The *Christianson* decision fully effectuates Congressional policy, by according exclusive jurisdiction to the Federal Circuit if a plaintiff must adjudicate patent issues to obtain the "overall success" of its claims. *Christianson* thus ensured that the Federal Circuit hears all appeals where a plaintiff's right to relief depends upon patent law issues. The Second Circuit's test demonstrably does not. The Second Circuit's misreading of *Christianson* would enable plaintiffs, by the simple expedient of artful pleading, to engage in appellate forum-shopping and deprive the Federal Circuit of patent-based appeals.

By adopting this new jurisdictional test, the Second Circuit was able to address a novel patent issue of sweeping dimensions, becoming the first appellate court to rule that purchasers of a patented product (who lack

standing to challenge the validity of a patent directly) can achieve standing to challenge a patent simply by attacking the patent under the antitrust laws. The Second Circuit thereby expanded the pool of litigants who can challenge patents, apparently unmoved by this Court's warning that antitrust laws should not be permitted to "chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits." *Walker Process Equip. Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 180 (1965) (Harlan, J., concurring). This important issue of patent policy should have been decided by the Federal Circuit.

I. The Court Of Appeals' Decision Conflicts With *Christianson v. Colt*

The court below failed to analyze whether plaintiffs' patent allegations (patent fraud and sham patent enforcement) and non-patent allegations (citizen petition) should be deemed separate "claims" or simply separate "theories" supporting a single claim. Instead, it treated the fact that plaintiffs' counsel had combined all the allegations into a one-count complaint as dispositive, and simply assumed that where a plaintiff frames its allegations as a single "count," the complaint contains only one "claim."

But *Christianson* requires a different and more discerning analysis, cutting through form and focusing on the substantive issue of what relief actually is being sought. 486 U.S. at 811 (construing a single antitrust count as encompassing two different antitrust claims); *see C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1367

(Fed. Cir. 1998) (explaining that one antitrust "count" actually consisted of "three separate claims"). Plaintiffs' allegation that fraud was perpetrated on the Patent Office is not just a "theory" underlying the same claim that, *many years later*, a citizen petition was filed with FDA. Regardless of the label attached to these different allegations, the citizen petition allegations do not, by themselves, give rise to the relief sought by plaintiffs for the "overarching scheme" that is actually alleged.

Plaintiffs' argument that they are the "master" of their complaint does not mean that a court should accept the self-serving labels that they place on their allegations, especially when the labels conflict with the complaint itself. This Court has warned that plaintiffs should not be permitted to determine appellate jurisdiction through their strategic pleading choices. *Christianson*, 486 U.S. at 809 n.3. *See also* S. REP. No. 97-275, at 19-20 (1981). If the Second Circuit had relied upon its own finding that patent allegations are "the linchpin" of plaintiffs' antitrust count, there would have been no question that the Federal Circuit has jurisdiction — regardless of whether the patent allegations were labeled "theories" or "claims."

Tellingly, when the Second Circuit stated its holding on the merits of this appeal, it flip-flopped and characterized plaintiffs' *Walker Process* "theory" as a "claim": "We therefore hold only that purchaser plaintiffs have standing to raise *Walker Process* claims . . . ." (Pet. App. 25a.) What had been a mere "theory" for jurisdictional purposes suddenly became a "claim" for standing purposes. The inconsistency of the court's characterization of plaintiffs' *Walker Process*

allegations underscores the problems inherent in a jurisdictional standard based on mere labels.

Christianson unambiguously held that the Federal Circuit has exclusive jurisdiction over an appeal as long as the plaintiff must litigate patent issues to obtain the "relief it seeks." Although the Second Circuit held that plaintiffs could plausibly state "a" claim that did not depend on patent law issues, "the" claim for relief asserted by plaintiffs plainly does depend on patent law issues. Their complaint seeks a judgment condemning "Defendants' actions as alleged herein" (including patent fraud), not a judgment condemning the filing of a citizen petition. Pet. App. 107a.

Moreover, plaintiffs seek relief based on defendants' "conduct as a whole" (Pet. App. 74a), including damages for many years before the citizen petition was even filed. Plaintiffs concede that they seek to recover additional damages based upon their patent allegations that would not be recoverable based upon their citizen petition allegations. Opp. Br. at 32.

Simply put, *Christianson* precludes the Second Circuit from asserting jurisdiction. Plaintiffs cannot obtain the relief they seek simply by proving their citizen petition allegation. The patent allegations are "the linchpin" of the "overarching" antitrust scheme that plaintiffs allege, and plaintiffs must prove their patent allegations to obtain the relief they seek.[1]

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1. Thus, plaintiffs' belated attempt to suggest that their case merely "*touches on*" patent issues (Opp. Br. at 3) is refuted by their own complaint.

In order to retain jurisdiction, the Second Circuit articulated a new rule. It held that the Federal Circuit lacks jurisdiction over a patent-based antitrust claim, as long as any non-patent theory advanced by the plaintiff could "plausibly constitute a Sherman Act violation" (Pet. App. 14a) — even if that violation was *not* the actual claim set forth in the complaint, and even if it could only provide a fraction of the "relief [plaintiff] seeks" in the complaint. The Second Circuit's new jurisdictional test flouts *Christianson*.

II. The Court Of Appeals' Decision Creates An Inter-Circuit Conflict

The Second Circuit's ruling cannot be reconciled with the decisions of other courts of appeals.

1. The Federal Circuit has categorically stated that a *Walker Process* claim is "subject to exclusive federal court jurisdiction under 28 U.S.C. § 1338(a) because the determination of fraud before the PTO necessarily involves a substantial question of patent law." (Pet. Br. at 21.) Plaintiffs argue that the Second Circuit's unpublished order in *In re Ciprofloxacin Hydrochloride Antitrust Litig.* (Opp. Br. at 28) is consistent with the Federal Circuit's unequivocal statement, because the Second Circuit transferred a case to the Federal Circuit that had a stand-alone *Walker Process* count while refusing to transfer related cases (which did not include any *Walker Process* counts).

In fact, the Second Circuit's *Ciprofloxacin* order confirms the conflict between the Second Circuit and the Federal Circuit. In *Ciprofloxacin* (as here), the

Second Circuit appears to have given dispositive weight to the labels attached to plaintiffs' allegations, and accepted the fact that the *Walker Process* count in that case was a separate "claim" (thereby triggering Federal Circuit jurisdiction) simply because it was pled as a separate count.

The *Ciprofloxacin* order cited by plaintiffs underscores how troublesome the Second Circuit's erroneous interpretation of *Christianson* is. Where a *Walker Process* claim is drafted as a separate count, the Second Circuit will remit jurisdiction to the Federal Circuit; but where a *Walker Process* claim is drafted as part of an omnibus count, the Second Circuit will retain jurisdiction. The Second Circuit's rule is devoid of substance, and an open invitation to forum-shopping through clever pleading.

2. Plaintiffs also misconstrue the import of the *U.S. Valves v. Dray* cases (Pet. Br. at 22-25). Under *Christianson*, Federal Circuit jurisdiction is triggered if a claim depends upon a contested patent question; patent matters that are not in dispute obviously do not trigger its jurisdiction. Plaintiffs argue that *U.S. Valves* is inapplicable, because all the breach of contract damages sought in that case involved sales of patented valves.

However, some damages related to valves that did not raise any *disputed* patent issues, because the defendant had already conceded that those valves were covered by the patents. *U.S. Valves, Inc. v. Dray*, 190 F.3d 811, 812 (7th Cir. 1999). The remaining damages related to valves that clearly raised disputed patent

issues. The Federal Circuit concluded that it had jurisdiction because "some of the valves" sold (i.e., the contested valves) would require the court to resolve issues of patent infringement. *U.S. Valves, Inc. v. Dray*, 212 F.3d 1368, 1372 (Fed. Cir. 2000). But under the Second Circuit's decision, the Federal Circuit lacks jurisdiction even if "some" of the relief sought requires adjudication of disputed patent issues.

3. Contrary to plaintiffs' arguments, the Second Circuit's ruling is also irreconcilable with *Davis v. Brouse McDowell, LPA*, 596 F.3d 1355 (Fed. Cir. 2010). *See* Pet. Br. at 25-26. There, the plaintiff alleged a "single claim for legal malpractice" based on two allegations — first, that the defendant failed to file foreign patent applications, and second, that the defendant failed to file U.S. patent applications. Like plaintiffs here, the *Davis* plaintiff sought to combine different factual allegations in a single claim, and then characterize them as alternative "theories" supporting the single claim.

The plaintiff argued that the Federal Circuit lacked jurisdiction because one of these "theories" (i.e., failure to file foreign applications) did not raise issues of U.S. patent law. Unlike the Second Circuit, however, the Federal Circuit did not give dispositive weight to the fact that the plaintiff had combined allegations of distinct conduct into a single count. Instead, it ruled that the single malpractice claim actually included two distinct claims, one of which raised U.S. patent law issues. Accordingly, the Federal Circuit had exclusive

jurisdiction. Under the Second Circuit's rule, it would not have had jurisdiction.[2]

III. The Court Of Appeals' Decision Will Undermine Congress' Purpose In Creating The Federal Circuit

The decision below also thwarts Congressional intent. Congress created the Federal Circuit to address two major problems plaguing patent appeals. First, it consolidated patent appeals in a single forum to develop uniform patent precedents in place of the existing hodge-podge of patent rulings in the regional circuit courts, which in some cases resulted in a "morass of conflict." IPO Amicus Br. at 16-18. Second, Congress sought to reduce "forum-shopping" by constraining the ability of patent litigants to steer an appeal to a specific circuit simply by the way in which a complaint was drafted. Pet. Br. at 27-29.

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2. Plaintiffs also cite *Clearplay, Inc. v. Abecassis*, 602 F.3d 1364, 1369 (Fed. Cir. 2010), for the proposition that the Federal Circuit does not have jurisdiction over a case simply because patent issues "are in the air." That is true, but irrelevant. *Clearplay* properly examined each claim raised by the plaintiff, and concluded that the court lacked jurisdiction because the relief sought under each claim could be obtained without adjudicating patent issues. Had the Second Circuit engaged in a similar analysis here, it would have concluded that the relief sought by plaintiffs was *not* obtainable without adjudicating substantial patent issues. But under the Second Circuit's test, the fact that patent issues are necessary to the relief actually sought by plaintiffs is not sufficient for the Federal Circuit to assert jurisdiction. *See also* IPO Amicus Br. at 10.

The decision below undercuts both Congressional goals. The new jurisdictional standard provides plaintiffs' counsel with virtually unfettered power to determine whether an appeal will be heard by the Federal Circuit or the regional circuit. In any lawsuit premised upon the allegation that the defendant wrongfully procured and enforced a patent, plaintiffs' counsel now have two paths open:

(a) If counsel wants the Federal Circuit to hear an appeal, he should allege a separate non-patent count. By labeling his patent-based allegations as a stand-alone "claim" in the complaint, counsel can ensure that the Federal Circuit will assert jurisdiction over the case. Under the Second Circuit's rule, counsel may add as many non-patent allegations as he wishes to the complaint without threatening the jurisdiction of the Federal Circuit — as long as the non-patent allegations are added as separate counts from the patent count.

(b) On the other hand, counsel can ensure that the appeal is heard by a regional circuit rather than the Federal Circuit simply by adding at least one *non-patent* allegation to the count that includes his patent-based claim. Under the Second Circuit's test, it does not matter how minor the non-patent allegation, or if the non-patent claim is based on different conduct at a different time causing a different legal injury. Nor does it matter if the patent claim is needed to obtain 99% of the damages alleged, or 99% of the injunctive relief sought. As long as the non-patent allegation could give rise to "a" claim by itself, then the Federal Circuit will be deemed to lack jurisdiction. Plaintiffs' counsel will exceed his role as master of his own complaint, and become master of the Federal Circuit docket.

As litigants pick-and-choose where to steer their cases, there will once again be thirteen different forums setting substantive patent law precedents, rather than just the Federal Circuit.[3] The lack of uniformity will not only undermine the "even-handedness nationwide in the administration of the patent laws," H.R. REP. No. 97-312, at 22 (1981), but will also inhibit innovation by undermining the confidence of businesses in the stability of patents. *See* BIO/PhRMA Amicus Br. at 15-16.

Unless this Court intervenes to correct the Second Circuit's decision, the bane of patent forum-shopping will again infect the appellate system, the formulation of uniform patent law will be compromised, and the statutory mandate that the Federal Circuit hear all appeals based "in whole or in part" on patent law issues will go unfulfilled.

---

3. Plaintiffs suggest that the Federal Circuit would simply apply regional circuit law to determine whether purchasers may challenge patents under the antitrust laws. But the Federal Circuit defers to regional circuit law only on "matters of procedural law that do not implicate issues of patent law." *E.g.*, *Bd. of Trs. v. Roche Molecular Sys., Inc.*, 583 F.3d 832, 840 (Fed. Cir. 2008). The question whether litigants who lack standing to challenge patents directly may challenge patents under the antitrust laws clearly "implicate[s] issues of patent law," and thus would be decided in a uniform manner. The standing issue in *Unitherm* cited by plaintiffs (Opp. Br. at 39), in contrast, did not implicate patent law issues.

CONCLUSION

Petitioners respectfully submit that their petition for a writ of certiorari should be granted.

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IN THE
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FERRING B.V., FERRING PHARMACEUTICALS, INC. AND AVENTIS PHARMACEUTICALS, INC.,
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MEIJER, INC., MEIJER DISTRIBUTION, INC., ROCHESTER DRUG CO-OPERATIVE, INC. AND LOUISIANA WHOLESALE DRUG CO., INC.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF THE BIOTECHNOLOGY INDUSTRY ORGANIZATION AND THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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INTEREST OF *AMICI CURIAE*[1]

1. The Biotechnology Industry Organization ("BIO") is a trade association representing over 1,100 companies, academic institutions, and biotechnology centers. BIO members are involved in research and development in healthcare, agricultural, environmental, and industrial products. The biotechnology industry currently has more than 370 products in clinical trials for treating more than 200 diseases. The vast majority of BIO members are small companies that have not yet brought a product to market or attained profitability.

The biotechnology industry is dependent on predictable and effective patent protection for the development of new technologies. Patents serve as the principal asset on which investors (such as venture capitalists) base decisions to invest in early-stage companies and fund research and development activities that will eventually bring new products to market. Predictability and transparency in the procurement and enforcement of patent rights provides the commercial certainty that is essential to support innovation in the biotechnology industry. BIO therefore wishes to promote the adoption and

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[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amici curiae*, their members, and their counsel, made any monetary contribution towards the preparation and submission of this brief. Petitioner Aventis Pharmaceuticals, Inc. is a member of both *amici curiae*, but has not authored the brief in whole or in part, nor contributed any money toward the brief's preparation and submission. Pursuant to Supreme Court Rule 37.2(a), *amici curiae* certify that counsel of record for both parties received timely notice of *amici curiae*'s intent to file this brief and have consented to its filing in letters on file with the Clerk's office.

application of standards for patent eligibility and enforcement that will ensure appropriate and consistent protection for the full range of inventions in the biotechnology sector.

2. The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association that represents the country's leading research-based pharmaceutical and biotechnology companies. PhRMA's members are dedicated to discovering medicines that enable patients to lead longer, healthier, and more productive lives. New medicines account for 40 percent of the lifespan increase between 1986 and 2000, see Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence From Longitudinal, Disease-Level Data From 52 Countries, 1982-2001*, 5 Int'l J. of Health Care Fin. & Econ. 47, 68 (2005), and member companies are the source of a majority of all new medicines that have been discovered and marketed. In the last decade, PhRMA's members have invested more than $400 billion to develop new medicines, including an estimated $45.8 billion last year alone. See PhRMA, *Pharmaceutical Industry Profile 2010*, at 26 (2010) ("Industry Profile"), *available at* http://www.phrma.org/files/attachments/Profile_2010_FINAL.pdf.

The ability of the Federal Circuit to provide uniformity in the patent laws, an issue raised in this case, is significant to PhRMA members because of the critical role intellectual property plays in incentivizing pharmaceutical research and development. A 2007 study estimated that the average research and development costs of bringing a new drug to market was approximately $1.3 billion in 2005, including the costs for unsuccessful drugs. See DiMasi & Grabowski, *The Cost of Biopharmaceutical R&D: Is*

Biotech Different?, 28 Managerial & Decision Econ. 469, 477 (2007). Another study notes that it takes approximately sixteen years to bring a new chemical entity to market and that "only a fraction of drugs in the R&D 'pipeline' ever succeed in making it to market." See Giaccotto et al., *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & Econ. 195, 196 & n.2 (2005). The patent laws reflect Congress's determination that the protections and corresponding incentives patents provide are essential to encouraging such costly, time-consuming, and high-risk research and development. With the creation of the Federal Circuit in 1982, Congress further recognized that uniformity and predictability in the patent laws is essential to meet these ends.

REASONS FOR GRANTING THE PETITION

The Second Circuit's decision strikes a serious blow to the uniformity and predictability of patent law that Congress sought to establish by giving the Federal Circuit exclusive jurisdiction over the vast majority of cases involving patent issues. As Congress understood well, stability in patent law is necessary to spur innovation by firms like those represented by *amici curiae*.

Consistent with Congress's intent, this Court made clear in *Christianson* v. *Colt Industries Operating Corp.*, 486 U.S. 800 (1988), that the Federal Circuit should hear virtually all appeals involving patent issues. The Court observed that the Federal Circuit has exclusive jurisdiction not only when "federal patent law creates the cause of action," but also whenever "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law." *Id.* at 809. Exclusive Federal

Circuit jurisdiction over patent issues is defeated only if the claim raising a patent issue could also be supported by a non-patent theory sufficient to achieve the "overall success of [the] claim." *Id.* at 810.

Despite that instruction, the Second Circuit took jurisdiction here over an antitrust claim that raises substantial patent law issues. The court of appeals based this jurisdiction on the ground that respondents' claim included a non-patent theory, even though that theory concerned just a portion of the wrongful conduct for which relief was sought. The decision below conflicts both with *Christianson* and with decisions of the Federal Circuit and Seventh Circuit. Those conflicts, which are fully explained in the petition, are reason enough for this Court to intervene.

This Court's review is especially needed, however, because the potential for litigants to manipulate the Second Circuit's test is obvious and endless. Claims that raise substantial questions of patent law can be crafted to avoid Federal Circuit review through formalistic choices in pleading. As a result, the uniformity of patent law that Congress intended is placed in jeopardy. Since its creation in 1982, the Federal Circuit has adapted many areas of patent law, such as inequitable conduct, to changing practices and technology. In contrast, the patent law of the regional circuits is largely stuck in the late-1970s. Yet, those regional decisions remain good law, and, to the extent they vary from the Federal Circuit's decisions (which they not infrequently do), many litigants will be motivated to craft their pleadings to obtain review by regional circuits rather than the Federal Circuit.

This increased uncertainty and opportunity for forum shopping will undoubtedly dampen innovation.

Especially in industries like biotechnology and pharmaceuticals, which require enormous investments in research and development, stability in the rules of decision is critical. Before such investments are made, innovators must weigh the potential costs and benefits. Doubts about the law that will apply to patent applications and existing patents will create uncertainty regarding the potential patent benefits of their efforts. Consequently, firms will invest fewer resources, and fewer advancements will be made. This dynamic led Congress to create the Federal Circuit. Now this Court's action is required to restore Congress's scheme.

ARGUMENT

I. THE DECISION BELOW DEFINES FEDERAL CIRCUIT JURISDICTION IN CONFLICT WITH THIS COURT'S PRECEDENTS AND THE FEDERAL CIRCUIT.

The Second Circuit asserted jurisdiction over this case by applying a standard that cannot be squared with this Court's case law or the decisions of other circuits, including the Federal Circuit—Congress's preferred arbiter of patent issues. For the sake of much-needed stability and to vindicate the Federal Circuit's special role in shaping patent law, this Court should clarify the scope of the Federal Circuit's exclusive jurisdiction.

1. Although plaintiffs' cause of action in this case arises under the antitrust laws, substantial issues of patent law unquestionably dominate the basis for the relief set forth in the complaint. Plaintiffs asserted a *single count* of monopolization based on the following alleged misconduct: (1) the fraudulent procurement of U.S. Patent No. 5,407,398 ("the '398 patent"); (2) the improper listing of the '398 patent in the U.S.

Food and Drug Administration (FDA) publication known as the "Orange Book"; (3) the prosecution of sham patent infringement litigation against competitors to forestall FDA approval of generic drug products claimed to be covered by the '398 patent; and (4) the filing of a sham citizen petition to further delay final FDA approval of the generic drug products. Pet. App. 59a-60a. Indeed, plaintiffs characterized their claim as based on an "anticompetitive scheme in which the '398 patent is the linchpin." *Id.* at 15a. The district court dismissed the complaint for failure to plead facts sufficient to state a claim of fraud, and lack of standing to challenge the '398 patent under the patent laws and antitrust laws.

Plaintiffs appealed to the Second Circuit. Even though the case implicates substantial and important patent issues, the Second Circuit held that it, rather than the Federal Circuit, had jurisdiction over the appeal. The court of appeals proceeded to hold that plaintiffs had standing and that the complaint adequately pled fraud, and therefore remanded the case. Pet. App. 8a, 16a, 25a-26a, 33a. The Second Circuit's jurisdictional holding forms the basis of the instant petition.

That holding turned on the fact that plaintiffs' antitrust claim, based primarily on patent issues, also included a non-patent "theory," *i.e.*, the allegedly sham citizen petition filing, which the court below found was "an issue independent of patent law." Pet. App. 12a. Thus, even though the court of appeals recognized that plaintiffs' three other theories "turn on substantial questions of patent law," and that "appellate jurisdiction would lie exclusively with the Federal Circuit if the plaintiffs' success solely depended on one or more of these theories," the court

asserted jurisdiction because one of plaintiffs' theories could "support the claim without raising substantial questions of patent law." *Id.* at 11a, 15a-16a. The court reached this decision despite the fact that the non-patent theory could not provide plaintiffs with all the relief sought, given that the citizen-petition allegation would not justify awarding damages for the time periods covered by the other allegations. The Second Circuit dismissed this critical factor—*i.e.*, whether the non-patent theory could achieve the claim's overall success—as "lack[ing] jurisdictional significance." *Id.* at 15a.

2. The decision below conflicts with this Court's construction of the Federal Circuit's jurisdictional statute. Congress specified that whenever a district court's jurisdiction "was based, in whole or in part," on 28 U.S.C. § 1338(a), any appeal must be taken in the Federal Circuit. 28 U.S.C. § 1295(a). Section 1338(a), in turn, gives district courts broad jurisdiction over "any civil action arising under any Act of Congress relating to patents." *Id.* § 1338(a). Taken together, these statutes reflect Congress's desire to empower the Federal Circuit as the authority over patent law, subject only to this Court's inherently limited supervision.

In *Christianson* v. *Colt Industries Operating Corp.*, 486 U.S. 800 (1988), this Court construed § 1338(a) to establish the governing test of Federal Circuit jurisdiction. In pertinent part, the Court explained that § 1338(a) includes cases in which "a well-pleaded complaint establishes" that "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." *Id.* at 809. Thus, if any one of a plaintiff's claims pleaded in the complaint includes

even a single element that involves patent law, the Federal Circuit has jurisdiction.

The *Christianson* Court acknowledged that a "well-pleaded claim" could involve alternative theories, under any one of which the plaintiff would be "'entitled to the relief [the claim] seeks.'" *Id.* at 810. In that situation, Federal Circuit jurisdiction does not lie if one of the theories does not implicate patent law. *Id.* After all, if a theory allows the plaintiff to obtain the relief sought by the claim without resolution of a patent issue, there might be no patent issue for the Federal Circuit to review and thus no comparative advantage in having the appeal handled by that court.

To be sure, the distinction between a "claim" and "theory" can be difficult to draw. As shown below, the distinction has engendered conflict among the circuits, and the Second Circuit reached the wrong decision here by mistaking a theory for a claim. See *infra* 9-11.

Several guiding principles arise out of *Christianson*. First, the *Christianson* Court explained that a non-patent theory defeats Federal Circuit jurisdiction only if it is a sufficient basis for "the *overall success* of [the] claim." 486 U.S. at 810 (emphasis added). In this sense, if the operative facts underlying the claim implicate patent law issues, the non-patent theory does not defeat Federal Circuit jurisdiction if it arises from only a portion of those facts, since such a theory could not determine the claim's "'overall success.'" *Id.* Similarly, Federal Circuit jurisdiction remains if the non-patent theory cannot support all the "'relief [the claim] seeks.'" *Id.*

Applying that standard, the *Christianson* Court held that the Federal Circuit did not have exclusive

jurisdiction in that particular case because the plaintiffs could have supported the entirety of their antitrust claim with several theories having nothing to do with patent issues. *Id.* at 813. Tellingly, these were different *legal* theories pertaining to the same operative facts, as opposed to different *factual* scenarios combined under a single count. *E.g.*, *id.* (claim alleged that defendant's agreement with other businesses to boycott plaintiffs' business was wrongful both under a patent theory (that defendant's patent was invalid) and under a theory involving no patent issue (that defendant had authorized plaintiffs' use of technology)). This implies that Federal Circuit jurisdiction would remain if the non-patent "theory" were, in reality, a separate claim, based on different operative facts. Cf. *Keene Corp.* v. *United States*, 508 U.S. 200, 212 (1993) (construing the term "claim" in 28 U.S.C. § 1500 with relation to "operative facts" and "relief requested").

Second, *Christianson* instructed courts to guard against a plaintiff's attempt to manipulate jurisdiction through artful pleading. 486 U.S. at 809 n.3 ("a plaintiff may not defeat § 1338(a) jurisdiction by omitting to plead necessary federal patent-law questions"). This is consistent with this Court's broader jurisdiction case law, which has favored rules that apply to a pleading's substance, rather than its form. For example, in determining whether a case filed in state court may be removed, the federal court must look beyond plaintiff's styling of his claims and ask whether a "well-pleaded" complaint would provide a basis for federal jurisdiction. *E.g.*, *City of Chi.* v. *Int'l Coll. of Surgeons*, 522 U.S. 156, 164 (1997); *Franchise Tax Bd.* v. *Constr. Laborers Vacation Trust*, 463 U.S. 1, 22 (1983). Thus, while a

plaintiff may be "master of the complaint," by choosing which substantive legal claims to assert, a plaintiff cannot avoid the jurisdiction that governs those claims by crafty pleading.

The Second Circuit's decision plainly disregarded these principles. The "theory" on which the Second Circuit based its jurisdiction was an independent factual occurrence joined with other discrete factual events under a single antitrust count. Pet. App. 11a-16a. As noted, the "theory" alleged that petitioners unlawfully extended a monopoly by filing a sham citizen petition to delay FDA approval of a generic drug in 2004. *Id.* at 63a, 93a. But, that is not a theory capable of sustaining the claim's "overall success," as *Christianson* requires. 486 U.S. at 810. Respondents' claim sought a ruling declaring defendants' enforcement of the patent unlawful and treble damages for the period beginning in 2001. Pet. App. 63a, 93a. However, the non-patent "theory" regarding the citizen petition would not entitle respondents to relief against enforcement of the patents or for damages related to the period before 2004. Consequently, that theory could not entitle plaintiffs to the "'relief [the claim] seeks,'" and did not provide a non-patent basis for the claim's "overall success." 486 U.S. at 810.

This mismatch between the "theory" undergirding the Second Circuit's putative jurisdiction and the relief the overall claim seeks reveals that, in fact, respondents pleaded multiple antitrust claims, and simply styled them as multiple "theories" in a single antitrust count. Under *Christianson*, as well as this Court's other jurisdiction cases, the Second Circuit should have looked beyond the complaint's labels and examined its substance. See *id.* at 809 n.3. Viewed in the proper light, it is clear that respondents could

only obtain all the "relief [the claim] seeks" if the district court addressed the patent law issues raised in their antitrust claims, since those concerned conduct beginning in 2001 and encompassed far more than the citizen petition. Those patent-law issues, which included a *Walker Process* antitrust claim, are the type that Congress meant to fall within the Federal Circuit's review.

3. Just as problematic, the Second Circuit's jurisdictional test is utterly incompatible with the Federal Circuit's test for its own jurisdiction. The conflict flows primarily from the Second Circuit's misperception of the distinction between "claims" and "theories."

Unlike the Second Circuit, the Federal Circuit has drawn the distinction correctly. Thus, in *Davis* v. *Brouse McDowell, L.P.A.*, 596 F.3d 1355 (Fed. Cir. 2010), the plaintiff pleaded a single count of malpractice against her former patent attorney, but alleged two distinct factual events that provided bases for recovery. First, the plaintiff alleged that the attorney neglected to file international patent applications in a timely fashion. *Id.* at 1357-58. Second, the plaintiff alleged that the attorney was negligent in his preparation of U.S. patent applications. *Id.* at 1358-59. The plaintiff argued that the Federal Circuit lacked jurisdiction on the ground that the two events constituted alternative "theories," one of which (*i.e.*, the failure to file the international application) did not implicate U.S. patent law. *Id.* at 1360. The Federal Circuit rejected the argument, concluding that the complaint "presents multiple *claims*." *Id.* (emphasis added). The Federal Circuit explained that a "'claim' is broadly defined as the 'aggregate of operative facts giving rise to a right enforceable by a court.'" *Id.*

(quoting *Black's Law Dictionary* 264 (8th ed. 2004)). Because the complaint presented "at least two distinct claims," one of which raised an issue of U.S. patent law, the Federal Circuit exercised jurisdiction. *Id.* at 1360-62.

Had the Second Circuit applied the Federal Circuit's straightforward distinction between claims and theories, it would have properly declined to assert jurisdiction. Even though respondents contended that they alleged a single antitrust claim comprising multiple theories, those theories are actually distinct sets of "operative facts" that would give rise to varying rights to relief. Therefore, under the Federal Circuit's *Davis* decision, plaintiffs' complaint would be read as involving separate claims. Most of those "claims" require proof of substantial questions of patent law, such as whether petitioners committed fraud or inequitable conduct before the United States Patent and Trademark Office ("PTO"). See Pet. App. 59a. Under *Christianson*, those patent law issues should have been reviewed by the Federal Circuit. Instead, the Second Circuit simply accepted the plaintiffs' labeling of these events as different "theories," and retained jurisdiction. This divergence in results warrants this Court's resolution.

4. This Court's intervention is especially necessary because the disagreement over Federal Circuit jurisdiction is not limited to the Second and Federal Circuits. As the petition shows, the Second Circuit's decision conflicts also with Seventh Circuit decisions. Pet. 21-27.

Moreover, practitioners and scholars have long bemoaned the uncertainty that plagues Federal Circuit jurisdiction. As one of the leading patent law scholars noted nearly 40 years ago, whether "a case

arise[s] under the patent laws" is "one of the darkest corridors of the law of federal courts and federal jurisdiction." Chisum, *The Allocation of Jurisdiction Between State and Federal Courts in Patent Litigation*, 46 Wash. L. Rev. 633, 638-39 (1971) (emphasis omitted). Although this Court more recently addressed the effect of counter-claims on Federal Circuit jurisdiction, *Holmes Group, Inc.* v. *Vornado Air Circulation Sys., Inc.*, 535 U.S. 826 (2002), *Christianson* remains the Court's last word on what constitutes a non-patent theory sufficient to avoid Federal Circuit appellate review. See 15A Wright et al., *Federal Practice and Procedure* § 3903.1, at 169-70 (2d ed. 1992) (noting that, although *Christianson* gave some guidance, "questions of 'arising under' jurisprudence . . . continue to befog Federal Circuit jurisdiction"). As the decision below demonstrates, more illumination is needed from this Court to cut through that fog.

II. THE DECISION BELOW UNDERMINES MUCH-NEEDED STABILITY AND PREDICTABILITY IN PATENT LAW.

The Second Circuit's erroneous test poses a serious threat to the stability and predictability in patent law that Congress intended. Its rule will allow plaintiffs to avoid Federal Circuit jurisdiction through formalistic choices in their pleading. This will exacerbate the forum shopping in patent law that Congress hoped to curtail. And, would-be innovators will have to account for increased legal uncertainty when deciding whether to make the enormous investments that precede so many advancements today, especially in the biotechnology and pharmaceutical fields.

1. The Second Circuit's test casts a shadow over Congress's vision for the Federal Circuit. Congress

created the Federal Circuit to "provide nationwide uniformity in [the] patent law" and to "make the rules applied in patent litigation more predictable." H.R. Rep. No. 97-312, at 20 (1981). By channeling patent cases into a single appellate forum, Congress intended that the resulting uniformity of decisions would foster technological growth and industrial innovation, as well as eliminate often "unseemly" forum-shopping that previously characterized patent litigation. *Id.*

The Second Circuit's decision, however, materially erodes the Federal Circuit's jurisdiction over cases that involve substantial questions of patent law. The court of appeals wrested jurisdiction away from the Federal Circuit based on a non-patent "theory" that was clearly ancillary to respondents' *Walker Process* claim and that could not provide respondents with all the "relief [the claim] seeks."

Under the Second Circuit's test, plaintiffs in other cases can similarly engage in artful pleading to avoid Federal Circuit review of patent issues. Common and recurring patent issues such as inventorship, validity, infringement, and enforceability are often pleaded along with non-patent causes of action sounding in tort, fraud, contract law, antitrust law, and bankruptcy law. According to the decision below, a plaintiff can avoid Federal Circuit jurisdiction simply by joining with each patent claim some allegation of wrongdoing that does not raise a patent issue—even if that allegation could not support all the relief the plaintiff seeks, and even if the allegation is fairly insubstantial. By this approach, many claims that raise substantial patent questions can be shielded from Federal Circuit review.

The Second Circuit's test will undoubtedly lead to more patent issues being diverted from the Federal

Circuit. This increases the potential for conflicts in patent law, as well as major patent issues being decided by generalist courts of appeals. Further, the variation will invite litigants to file suit in a district court that offers opportunities to appeal to the forum they perceive as most favorable. In light of the broad availability of declaratory relief actions by putative patent infringers, see *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118 (2007), the risk of unseemly races to the courthouse and blatant forum shopping are particularly aggravated unless the Second Circuit's rule is reviewed and reversed. These are problems Congress meant for Federal Circuit jurisdiction to solve.

2. While Congress intended uniformity in all areas of the patent law, uniformity is especially important in *Walker Process* antitrust disputes, such as the instant case. A *Walker Process* claim alleges that a defendant obtained an unlawful monopoly by "knowingly and willfully misrepresenting facts" to the PTO in prosecuting a patent. *Walker Process Equip., Inc.* v. *Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965). Although it arises under antitrust laws, a *Walker Process* claim inherently involves an inquiry into patent issues, such as the basis for the PTO's issuance of the patent and the materiality of the allegedly misrepresented facts. *E.g.*, *Dippin' Dots, Inc.* v. *Mosey*, 476 F.3d 1337, 1346-47 (Fed. Cir. 2007). For that reason, *Walker Process* claims raise "issue[s] unique to the patent law." *Unitherm Food Sys., Inc.* v. *Swift-Eckrich, Inc.*, 375 F.3d 1341, 1357 (Fed. Cir. 2004), *rev'd on other grounds*, 546 U.S. 394 (2006). Indeed, patent issues were the "linchpin" of respondents' claims here. Pet. App. 15a. Nonetheless, the Second Circuit asserted jurisdiction based on a tangential, factually separate non-patent alle-

gation, largely ignoring the patent issues at the heart of the case.

The importance of the Federal Circuit's leading role in shaping *Walker Process* law is underscored by the potential for treble damages in *Walker Process* claims. The potential for such severe sanctions means that uncertainty in this area can chill technological growth and innovation. The Federal Circuit is best-situated to supervise a claim based on *Walker Process* with proper sensitivity to other patent doctrines that bear on incentives to innovate. But the decision below deprives the Federal Circuit of that role and serves as a blueprint for pleading that avoids Federal Circuit review. This Court's intervention is urgently needed to protect against these untoward consequences.

3. The law of inequitable conduct is another patent doctrine whose orderly development by the Federal Circuit would be disrupted by the decision below. Inequitable conduct is a claim that a patent, even if it is valid and infringed, is unenforceable because the patent holder misrepresented or concealed information from the PTO while obtaining the patent. See *Critikon Inc.* v. *Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997); 37 C.F.R. § 1.56. Inequitable conduct requires proof of materiality, a quintessential patent law issue concerning how the misrepresented or concealed information relates to the patent claims that the inventor was pursuing. See, *e.g.*, 37 C.F.R. § 1.56(b).

The Federal Circuit has recognized that "the habit of charging inequitable conduct in almost every major patent case has become an absolute plague." *Burlington Indus., Inc.* v. *Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). To combat this abuse, the Federal Circuit has rejected a gross negligence

standard for finding inequitable conduct and instead held that both deceptive intent and materiality must be shown in order to render a patent unenforceable. *Kingsdown Med. Consultants, Ltd.* v. *Hollister, Inc.*, 863 F.2d 867, 873-74 (Fed. Cir. 1988). And, more recently, the Federal Circuit clarified that both deceptive intent and materiality must be proven by clear and convincing evidence. See, *e.g.*, *Star Scientific Inc.* v. *R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365-66 (Fed. Cir. 2008).

As a result, the Federal Circuit's strict inequitable conduct standards now differ markedly from those found in regional circuits. After the Federal Circuit's creation in 1982, most regional circuits had no opportunity to revisit their inequitable conduct doctrines, and so their less-exacting gross negligence tests persist. See, *e.g.*, *Digital Equip. Corp.* v. *Diamond*, 653 F.2d 701 (1st Cir. 1981); *True Temper Corp.* v. *CF&I Steel Corp.*, 601 F.2d 495 (10th Cir. 1979); *Int'l Tel. & Tel. Corp.* v. *Raychem Corp.*, 538 F.2d 453 (1st Cir. 1976)). Though decades old, these cases remain good law unless altered by the en banc court of appeals or by this Court, either of which is exceedingly rare, and litigants asserting inequitable conduct claims would undoubtedly prefer the benefit of those cases.

To date, the uncertainty created by these decisions has been kept in check by the regional circuits' limited opportunities to decide inequitable conduct issues. Under the Second Circuit's jurisdictional standard, however, the floodgates could break open. Litigants could cast claims of inequitable conduct as one "theory" in support of any number of non-patent causes of action sounding in fraud, rather than as a separate, independent "claim." Even though most inequitable conduct disputes necessarily turn on

substantial patent law issues (materiality requires an inquiry into claim construction, the scope and content of the prior art, and questions of potential invalidity based on, for example, anticipation and obviousness), such issues could be shielded from Federal Circuit review under the Second Circuit's erroneous rule.

Moreover, uncertainty in inequitable conduct law creates unpredictability in other aspects of patent litigation. For example, because the Federal Circuit's inequitable conduct standard includes a scienter element and sounds in fraud, the Federal Circuit requires plaintiffs to plead inequitable conduct claims with the particularity required by Federal Rule of Civil Procedure 9(b). See, *e.g.*, *Exergen Corp.* v. *Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009); *Ferguson Beauregard/Logic Controls, Div. of Dover Res., Inc.* v. *Mega Sys., LLC*, 350 F.3d 1327, 1344 (Fed. Cir. 2003). It is not clear, however, whether the regional circuits' different inequitable conduct standards require this same level of detailed factual pleading in a complaint. The possibility that less-detailed pleading suffices in those circuits creates additional incentive for litigants to forum shop. Patent enforceability should not be dependent on an accident of judicial venue.

Recognizing the need for clarity in these doctrines, the Federal Circuit recently granted rehearing en banc to provide guidance on the materiality standard in inequitable conduct, and its relationship to the doctrines of unclean hands and fraud. See *Therasense, Inc.* v. *Becton, Dickinson & Co.*, No. 2008-1511, 2010 WL 1655391 (Fed. Cir. Apr. 26, 2010) (per curiam). It is, therefore, particularly important that the Court reverse the decision below and prevent regional circuits from disrupting the Federal Circuit's

efforts to bring uniformity to these recurring patent law issues.

4. This Court should not underestimate the difficulties regional circuits would encounter in trying to apply their own antiquated patent law to current cases. By definition, patent cases deal with advancements in science and technology. As the court with almost exclusive jurisdiction over patent appeals since the early 1980s, the Federal Circuit has developed experience and expertise in the underlying sciences and the unique patent law issues raised by cutting-edge innovations.

By contrast, patent law in the regional circuits has largely remained frozen since the creation of the Federal Circuit. The Second Circuit decision here opens the door to important patent issues being decided by regional circuits that lack familiarity with rapidly advancing technology or the governing patent law. This will undermine the certainty Congress sought to establish by centralizing the development of patent law in the Federal Circuit. And, it will deprive practitioners and industry of the Federal Circuit's unique capability to adapt the law to technological advances. Perhaps no firms stand to lose more than biotechnology and pharmaceutical firms, which have played such an important role in this country's economic growth in the past 25 years and which will continue to play central roles in the country's economy for the foreseeable future.

To be sure, the regional circuits occasionally can decide patent issues. In *Holmes Group Inc.* v. *Vornado Air Circulation Systems Inc.*, 535 U.S. 826 (2002), this Court held that regional circuits have jurisdiction over patent issues raised in counterclaims, rather than in a well-pleaded complaint. But there is no dispute that Congress created the Federal

Circuit to bring a large measure of uniformity to patent law, and that goal has been largely achieved. Regional circuits have exercised *Vornado*-based appellate jurisdiction over patent counterclaims only infrequently. The decision below, however, threatens to break off a much larger piece of Federal Circuit jurisdiction. To prevent this unwarranted erosion of that court's exclusive grant of jurisdiction, this Court should grant review.

5. Because the decision below introduces substantial uncertainty into patent-law jurisdiction, it will needlessly increase the costs of patenting new innovations, and therefore deter the development of new, often life-saving, products.

In many industries—with biotechnology and pharmaceutical firms being chief among them—innovations result only because of enormous investments into research and development. As noted, on average, developing and securing regulatory approval for a new drug or biologic costs approximately $1.3 billion. See DiMasi & Grabowski, *supra*, at 477. In addition, the journey from research and development to regulatory approval averages approximately 16 years. See Giaccotto et al., *supra*, at 196 & n.2; see also Industry Profile at 27. During that time, the firm earns no return on its investment. And, the firm may never earn any return since just "very few drugs that enter development ever achieve final marketing approval." Industry Profile, at 27. Even with approval, just two in ten medicines ever produce revenues that match or exceed average R&D costs. See Vernon et al., *Drug development costs when financial risk is measured using the Fama-French three-factor model*, Health Econ. (Aug. 2009), http://dx.doi.org/10.1002/hec.1538; see also Industry Profile at "Key Facts."

Given those realities, firms in these industries must undertake a careful cost-benefit analysis before embarking on a new line of research, and decisions are made years before any hope of actually creating a commercial product. For that reason, stability and predictability in the rules that govern potential litigation are absolutely essential. Congress realized this as it set up the Federal Circuit, intending it to develop a uniform, expertise-based body of patent law to guide innovation. By adopting a jurisdictional standard that makes it far more likely that a plaintiff could take a case to any circuit, particularly given the declaratory judgment device, the decision below will require innovators to keep tabs on differing laws across the regional circuits. Firms will have to factor in this uncertainty in their cost-benefit analysis, and consequently, discount the potential reward for years of hard work. This is precisely the result Congress sought to avoid. Only this Court can remedy the injury to Congress's intent created by the Second Circuit's wayward jurisdictional ruling in this case.

CONCLUSION

For these reasons, and those stated by petitioner, the petition for a writ of certiorari should be granted.

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April 29, 2010

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APR 29 2010

No. 09-1175

IN THE
Supreme Court of the United States

FERRING B.V., FERRING PHARMACEUTICALS, INC., and AVENTIS PHARMACEUTICALS, INC.,

Petitioners,

v.

MEIJER, INC., MEIJER DISTRIBUTION, INC., ROCHESTER DRUG CO-OPERATIVE, INC., and LOUISIANA WHOLESALE DRUG CO., INC.,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

MOTION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF AND BRIEF OF INTELLECTUAL PROPERTY OWNERS ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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MOTION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF

Intellectual Property Owners Association ("IPO") moves for leave to file a brief as *amicus curiae* supporting petitioners Ferring B.V. et al.

Amicus curiae IPO is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in U.S. intellectual property rights. IPO's membership includes more than 200 companies and a total of nearly 11,000 individuals who are involved in the association either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO regularly represents the interests of its members before Congress and the PTO and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law. The members of IPO's Board of Directors must approve the filing of a brief by a three-fourths majority.

IPO believes that it can provide the court with perspectives that may not be provided by the parties or other *amicii*. IPO's Board of Directors includes chief patent counsel for companies in all major industries. The proposed IPO brief has been approved by chief patent counsel from diverse industries including computers, software, chemicals and pharmaceuticals.

The proposed IPO brief addresses the question of whether the Second Circuit's new jurisdictional standard is inconsistent with this Court's decision in *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800 (1988), and in conflict with decisions of the Federal Circuit and Seventh Circuit. In finding that it, not the Federal Circuit, had jurisdiction over the patent-related Sherman Act claims asserted by Plaintiffs, including *Walker Process* claims, simply because a non-patent-related Sherman Act claim also was included in the same count, the Second Circuit disregarded Congress's intent in creating the Federal Circuit as well as this Court's decision in *Christianson* which supported the Federal Circuit's jurisdiction over patent issues.

IPO believes that its brief could be helpful to the Court. IPO therefore requests that the Court grant this motion for leave to file in support of petitioners Ferring B.V., et al.

Consent to file this brief was requested of both parties in writing on April 7, 2010. Ferring B.V., et al. has granted consent. However Meijer, Inc. et al. has not.

Respectfully submitted,

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QUESTION PRESENTED

Amicus curiae Intellectual Property Owners Association addresses the following issue only:

Whether the Second Circuit's new jurisdictional standard is inconsistent with this Court's decision in *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800 (1988), which held that the Federal Circuit has exclusive jurisdiction in any patent-based case in which patent issues must be resolved in order for plaintiffs to achieve the overall success of their claim and obtain all the damages (or other relief) they seek, and in conflict with the decisions of the Federal Circuit and Seventh Circuit, which have followed this Court's *Christianson* standard.

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INTEREST OF AMICUS CURIAE

Amicus curiae Intellectual Property Owners Association ("IPO")[1] is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in U.S. intellectual property rights. IPO's membership includes more than 200 companies and more than 11,000 individuals who are involved in the association either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO members receive about thirty percent of the patents issued by the U.S. Patent and Trademark Office ("PTO") to U.S. nationals. IPO regularly represents the interests of its members before Congress and the PTO and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law. The members of IPO's Board of Directors, which approved the filing of this brief, are listed in the Appendix.[2]

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1. *Amicus curiae* gave appropriate notice to both parties and requested consent to file this brief. Consent was granted from the Petitioners, but not from the Respondents. A motion for leave to file a brief *amicus curiae* is attached. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae*, or its counsel made a monetary contribution to its preparation or submission.

2. IPO procedures require approval of positions in briefs by a three-fourth majority of directors present and voting.

SUMMARY OF THE REASONS FOR GRANTING THE PETITION

Congress conferred "exclusive jurisdiction" in the U.S. Court of Appeals for the Federal Circuit over all appeals based "in whole or in part" on patent claims. 28 U.S.C. § 1295(a)(1) (2006). The federal courts consistently have interpreted this mandate to vest the Federal Circuit with *exclusive* appellate jurisdiction over patent-based antitrust claims, including claims based on the Court's *Walker Process* decision.[3]

This consistent line of authority fulfills both the language of the Federal Circuit's enabling act[4] and the intent of Congress in creating the Federal Circuit. Congress created the Federal Circuit as an intermediate appellate court to bring uniformity to judicial interpretation of the Patent Act. While not every matter involving a patent must be heard by the Federal Circuit, Congress struck the balance heavily in favor of cases reaching the Federal Circuit when they involve patent issues.

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3. A *Walker Process* claim is a type of Sherman Act Section 2 claim based, *inter alia*, on proof that a patentee "obtained [a] patent by knowingly and willfully misrepresenting facts to the" PTO thus forfeiting the right to exclude conveyed by the patent grant. *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 175–77 (1965).

4. The Federal Circuit was created by the Federal Courts Improvement Act of 1982. Pub. L. No. 97-164, 96 Stat. 25 (1982).

Since its creation in 1982, the Federal Circuit has served this purpose by resolving or aiding resolution of a number of patent issues that had been interpreted differently among and between the regional circuits and the PTO, including the scope of attorney-client privilege over patent prosecution matters and how patent claims should be construed. This increase in patent law uniformity has allowed prospective intellectual property owners to develop and protect useful inventions based on a relatively settled and consistent set of legal standards. Patent holders' prior uncertainty due to the fact that their patents could be judged by any one of a differing set of regional circuit standards largely has been eliminated.

The decision of the Second Circuit below is contrary to Congress's grant of jurisdiction to the Federal Circuit and conflicts with nearly three decades of authority interpreting that grant. The Second Circuit found that it, not the Federal Circuit, had jurisdiction over the patent-related Sherman Act claims asserted by Plaintiffs, including a *Walker Process* claim, simply because a non-patent-related Sherman Act claim also was included in the same count. Pet. App. 15a–16a.[5] The Second Circuit reached this conclusion as a result of misapprehending Plaintiffs' patent-related *claims* to relief to be "theories" of an omnibus Sherman Act claim. In so doing, the Second Circuit misconstrued this Court's decision in *Christianson v. Colt Industries Operating Corp.*, 486 U.S. 800, 811 (1988). Pet. App. 15a–16a.

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5. The Second Circuit's decision below is reprinted at Pet. App. 1a–34a.

The Second Circuit's decision in no way follows from this Court's decision in *Christianson*. Indeed, the Second Circuit turned on its head this Court's ruling that the Federal Circuit should have jurisdiction if any element of one of a plaintiff's claims "necessarily depends on resolution of a substantial question of federal patent law . . . ." *Christianson*, 486 U.S. at 808–09. And, in so doing, the Second Circuit wrested from Congress and the courts the question of which appeals court will hear patent-related antitrust claims and put it entirely in the hands of litigants. Under the Second Circuit's rule, if the antitrust plaintiff wishes the Federal Circuit to hear its appeal, it will separate *Walker Process* and other patent-related claims from its other counts. If the antitrust plaintiff wishes a regional circuit court to hear its appeal, it will bundle its *Walker Process* claim in a single count with non-patent-related antitrust claims and characterize them as different "theories" to the same relief. This result will undermine Congress's intention of creating national uniformity in the patent laws and the handling of patent-related antitrust claims and other claims that are based in part on the patent laws.

The Second Circuit's decision not only is contrary to the intent of Congress as expressed in the Federal Circuit's enabling act and this Court's decision in *Christianson*, it also creates a conflict among the circuit courts. The Federal Circuit has held that it has exclusive appellate jurisdiction over a plaintiff's *Walker Process* claim "because the determination of fraud before the PTO necessarily involves a substantial question of patent law." *Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1329, 1330 n.8 (Fed. Cir. 2008).

Similarly, where resolution of a plaintiff's breach of contract claim required the court to make a patent infringement determination, the Seventh Circuit found that the Federal Circuit had exclusive appellate jurisdiction. *U.S. Valves, Inc. v. Dray*, 190 F.3d 811, 813–15 (7th Cir. 1999).

In all, the decision below is at odds with statutory authority, the precedent of this Court, and in conflict with the rulings other circuit courts. *Amicus curiae* IPO, therefore, respectfully requests that the Court grant *certiorari*.

REASONS FOR GRANTING THE PETITION

I. THE SECOND CIRCUIT'S DECISION IS INCONSISTENT WITH *CHRISTIANSON* AND IN CONFLICT WITH DECISIONS OF THE FEDERAL CIRCUIT AND SEVENTH CIRCUIT.

A. Under *Christianson*, Appellate Jurisdiction Was Fixed In The Federal Circuit Based On Plaintiffs' Complaint.

A proper application of *Christianson* would fix exclusive appellate jurisdiction in the Federal Circuit because Plaintiffs' complaint included no less than three patent-related antitrust claims.

In *Christianson*, this Court explained the two-part test that applies to determining the Federal Circuit's appellate jurisdiction. First, the court applies the "well-pleaded complaint" rule to determine which of the plaintiff's claims possibly can confer "arising under"

patent jurisdiction. 486 U.S. at 807–08.[6] Second, the court analyzes the well-pleaded claims to see if any fall in two categories belonging exclusively to the Federal Circuit. *Id.* at 808–09. Category I claims encompass those in which federal patent law creates the cause of action (*e.g.*, patent infringement claims). *Id.* Category II claims encompass those in which "plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that patent law is a necessary element of one of the well-pleaded claims." *Id.*

Significantly, only one element of a well-pleaded claim needs to "depend on resolution of a substantial question of patent law" for the entire well-pleaded claim to arise under the patent laws. *Id.*; *see also Franchise Tax*, 463 U.S. at 8 n.8 (although enabling statutes are often significantly narrower, federal question jurisdiction can extend to any case where a latent federal "ingredient" might be dispositive of the outcome of the case).

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6. [W]hether a case is one arising under [federal law], in the sense of the jurisdictional statute, . . . must be determined from what necessarily appears in the plaintiff's statement of his own claim in the bill or declaration, unaided by anything alleged in anticipation of avoidance of defenses which it is thought the defendant may interpose.

Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust, 463 U.S. 1, 10 (1983); *see also Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 830–32 (2002) (determining the same in the context of patent law cases).

1. Plaintiffs' Well-Pleaded Complaint Includes At Least Four Different Claims; Three Of Which "Depend On Resolution Of A Substantial Question Of Patent Law."

(a) The Distinction Between The Citizen's Petition And Patent-Related Claims Is Demonstrated By The Relief Associated With Each.

Plaintiffs' single-count class action complaint alleges at least four distinct claims to relief, including that Defendants:

(1) violated Section 2 of the Sherman Act by procuring U.S. Patent No. 5,047,398 (the " '398 patent"), relating to a pharmaceutical product called desmopressin acetate, by fraud under *Walker Process* by knowingly and willingly misrepresenting facts to the PTO, Pet. App. 77a–84a (¶¶ 50–74);

(2) violated Section 2 by improperly listing the '398 patent in the U.S. Food and Drug Administration ("FDA") publication known as the Orange Book, Pet. App. 84a–87a (¶¶ 75–85);

(3) violated Section 2 by filing and prosecuting a baseless sham patent infringement litigation against generic drug manufacturers to delay FDA approval of competing generic tablets from 2002 to February 2005, Pet. App. 87a–91a (¶¶ 86–98); and,

(4) violated Section 2 by filing an unfounded citizen's petition with FDA in February 2004 to delay further final FDA approval of generic competition, Pet. App. 91a–100a (¶¶ 99–125).

Plaintiffs listed each one of these instances of conduct under the heading "*violations*," separately referred to each instance of conduct using subparagraphs a–d in paragraph 144 of their complaint, and alleged that they were injured by "Defendants' antitrust *violations*." Pet. App. 104a–07a (¶¶ 144, 147) (alleging four Section 2 violations based on the foregoing conduct) (emphasis added).

Further, in their prayer for relief, Plaintiffs requested the court find that "Defendants' *actions*" violated Section 2 and award them damages for the overcharges they sustained. Pet. App. 107a, 108a (prayer (ii) & (iii)) (emphasis added). Plaintiffs characterized their injury as paying more for desmopressin acetate tablets than they would have absent Defendants' antitrust "*violations*." Pet. App. 107a (¶ 147) (emphasis added). Plaintiffs' injury allegedly began in February 2001—three years before Defendants submitted the citizen's petition to FDA—and continued until at least July 2005 when the first generic competitor entered the desmopressin acetate tablet market. Pet. App. 103a, 63a, 100a, 102a (¶¶ 134, 15, 122, 131–133).

Under the Court's decision in *Christianson*, each distinct instance of wrongful conduct alleged in Plaintiffs' complaint below constitutes an independent claim to relief because, if proved, each would entitle Plaintiffs to different relief. As this Court explained: if a plaintiff only may

recover the "relief it seeks" for reasons that "depen[d] on resolution of a substantial question of federal patent law," the claim arises under the patent laws. *Christianson*, 486 U.S. at 809–10; *see also City of Chicago v. Int'l Coll. of Surgeons*, 522 U.S. 156, 164 (1997) (a case arises under federal law for purposes of federal-question jurisdiction if the plaintiff's "right to relief necessarily depends on resolution of a substantial question of federal law"). Depending on which well-pleaded claims Plaintiffs prevail, they will obtain different relief. For example, if Plaintiffs' patent-related antitrust claims fail but their citizen's petition claim succeeds, Plaintiffs' relief will be limited to damages for the injury period beginning in 2004 when Defendants filed the sham citizen's petition and will not reach back to 2001 when the class period begins. Pet. App. 63a, 93a–94a, 100a, 103a (¶¶ 15, 105, 121–22, 134). If, however, Plaintiffs succeed on their *Walker Process* claim, they would be entitled to damages for the injury period starting in 2001 at the beginning of the class period. Pet. App. 63a, 100a, 103a (¶¶ 15, 121–22, 134).[7]

Each of the *Walker Process*, Orange Book, and sham litigation claims in the present case necessarily "depend[s] on resolution of a substantial question of patent law."[8]

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7. These potential results are each based on the *actual claims* in Plaintiffs' *well-pleaded complaint*, not on an unpleaded claim that could have been adjudicated at trial. *Cf. Holmes*, 535 U.S. at 832 n.3 (explaining that "the Federal Circuit's jurisdiction, like that of the district court, 'is determined by reference to the well-pleaded complaint, not the well-tried case.' " (*quoting Christianson*, 486 U.S. at 814)).

8. Of course, Plaintiffs as "the master of the complaint" could have chosen to "esche[w] claims based on federal [patent] law . . . , to have the cause heard in" the regional circuit on appeal. *See Holmes*, 535 U.S. at 831 (quotations and citations omitted).

This is not disputed. Pet. App. 10a–11a (Second Circuit decision below concluding that all three of these claims "turn on substantial questions of patent law"). Accordingly, any one of these claims alone should have been sufficient to vest jurisdiction in the Federal Circuit. *See Christianson*, 486 U.S. at 807–09. The Second Circuit, however, improperly characterized these claims to relief as "theories" under a Section 2 Sherman Act claim and therefore wrongly concluded that it had appellate jurisdiction. Pet. App. 10a–11a, 15a–16a.

Indeed, the Federal Circuit, applying *Christianson*, recently validated this approach in a decision finding regional circuit jurisdiction where plaintiff could obtain all of the relief it sought under six state-law claims without the resolution of any patent issues. *ClearPlay, Inc. v. Nissim*, No. 09-1471, slip op. at 10–11 (Fed. Cir. Apr. 21, 2010). *ClearPlay* involved breach of contract, tortious interference, and unfair competition claims arising, *inter alia*, out of a failed license agreement that had settled earlier patent infringement litigation. *Id.* at 7–8. Unlike *U.S. Valves*, a breach of contract case that required a determination of whether certain products were within the scope of a patent, *U.S. Valves*, 190 F.3d at 813–15, the breach of contract claims in *ClearPlay* included claims for breach of provisions that did not required any patent-based determination, *ClearPlay*, No. 09-1471, slip op. at 8–10. Plaintiff ClearPlay's other state law claims also did not require resolution of any patent issue. *Id.* Accordingly, the Federal Circuit—looking to each claim to determine if it required resolution of a patent issue—correctly found it had no jurisdiction over the appeal. *Id.* at 10–11. This is precisely the analytical approach that the Second Circuit should have followed below.

(b) The Alleged Sherman Act Violations Stand As Independent Claims, Not "Theories."

Plaintiffs' *Walker Process*, Orange Book, sham litigation, and sham citizen's petition claims should not be aggregated to determine whether there is a single, composite violation of Section 2 of the Sherman Act. Rather, each one of the four instances of wrongful conduct alleged in Plaintiffs' complaint establishes a separate violation of Section 2, and thus a separate claim to relief. *See, e.g., Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1069–70 (Fed. Cir. 1998) (*Walker Process* claim elements); *In re Buspirone Patent & Antitrust Litig.*, 185 F. Supp. 2d 363, 370–73 (S.D.N.Y. 2002) (Orange Book claim elements); *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60–61 (1993) ("*PRE*") (sham litigation or *PRE* claim elements); *Primetime 24 Joint Venture v. Nat'l Broadcasting Co., Inc.*, 219 F.3d 92, 100–01 (2d Cir. 2000) (sham citizen's petition claim elements).

Plaintiffs' citizen's petition claim is logically and factually distinct from their patent-based Section 2 claims. The citizen's petition claim is founded on Defendants' alleged attempt to persuade the FDA to withhold regulatory approval for generic competition through a sham regulatory petition. Pet. App. 92a–100a (¶¶ 99–125). The citizen's petition urged the FDA to require more testing before determining that the generic products were bioequivalent to Defendants' reference listed drug product. Pet. App. 94a (¶ 106). Defendants submitted the petition in 2004, well after

the '398 patent had been obtained, listed in the Orange Book, and asserted against Defendants' generic competitors. Pet. App. 93a–94a (¶ 105). Had no patent on desmopressin acetate ever been granted, Defendants still could have attempted to persuade the FDA to withhold approval of the generic products on the basis of inadequate bioequivalence testing. In contrast, Plaintiffs' other three claims all are based on allegations that Defendants took unlawful actions with respect to the '398 patent—fraudulently obtaining it at the PTO and then wielding the patent monopoly against generic competitors. *See* Pet. App. 77a–91a (¶¶ 50–98). These are separate claims, based on separate acts, taken at separate times.

(c) The Motion To Dismiss Standard Exemplifies Why Plaintiffs Have Four Separate Claims.

Federal Rule of Civil Procedure 12(b)(6) provides another lens by which the Court can determine that Plaintiffs' four claims are discrete. Rule 12(b) provides a mechanism for asserting defenses by motion against "a claim for relief," allowing dismissal where the allegations "fail to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b) & 12(b)(6).

Were patent-related antitrust claims such as *Walker Process* and sham litigation merely "theories" underlying an omnibus Section 2 claim for relief, each individually would not be the proper subject of a Rule 12(b)(6) motion. Yet, federal district courts consistently treat *Walker Process* and sham litigation claims separately for Rule 12(b)(6) purposes, often granting

dismissal as to one and denying it as to the other. *See e.g., Novo Nordisk of N. Am., Inc. v. Genentech, Inc.*, 885 F. Supp. 522, 527 (S.D.N.Y. 1995) (granting motion to dismiss plaintiff's sham litigation claim but denying motion as to plaintiff's *Walker Process* claim); *see also Seiko Epson Corp. v. Glory So. Software Mfg., Inc.*, No. 06-477, 2010 WL 256505, at *3–5 (D. Or. Jan. 19, 2010) (dismissing sham litigation counterclaim but not *Walker Process* counterclaim); *Amgen, Inc. v. F. Hoffmann-La Roche Ltd.*, 480 F. Supp. 2d 462, 465, 471 (D. Mass. 2007) (dismissing sham litigation counterclaim but not *Walker Process*, monopolization, and attempted monopolization counterclaims, among others). *Walker Process* and sham litigation claims are subject separately to Rule 12(b)(6) motions because they are separate claims for relief.

2. There Were No Patent-Related Claims In *Christianson*; This Case Is Different.

Plaintiffs' complaint is not like the one that was at issue in *Christianson*. The claims to relief in *Christianson* did *not* depend on a substantial question of patent law. The *Christianson* plaintiff sought relief because of defendant's monopolistic conduct and organization of a group boycott. *See Christianson v. Colt Indus. Op. Corp.*, 822 F.2d 1544, 1556–58 (Fed. Cir. 1987) (Federal Circuit deciding merits of case despite finding that it lacked jurisdiction over the appeal), *rev'd on other grounds* 486 U.S. 800, 818 (1988) (this Court reversing because "[o]ur agreement with the Federal Circuit's conclusion that it lacked jurisdiction, compels us to disapprove of its decision to reach the merits anyway 'in the interest of justice.' "). No patent validity questions, nor any other substantial questions of

patent law, were necessary to the resolution of the *Christianson* plaintiff's affirmative claims for relief. *Christianson*, 822 F.2d at 1559, *rev'd on other grounds*, 486 U.S. 800. The "patent issues" in *Christianson* arose only as a response to an anticipated defense of trade secret validity. *Christianson*, 822 F.2d at 1559, *rev'd on other grounds*, 486 U.S. 800; *see also* A.J. Gajarsa & L.P. Cogswell, III, *The Federal Circuit and the Supreme Court*, 55 Am. U. L. Rev. 821, 824 (2006) (Federal Circuit Judge Gajarsa explained that "Christianson had brought an antitrust suit against Colt, and issues of patent law were implicated only by part of Colt's defense against those charges"). Because the "patent issues" in *Christianson* were related to a response to a defense, as opposed to an affirmative claim for relief, they could not serve as a basis for vesting appellate jurisdiction in the Federal Circuit. *Christianson*, 486 U.S. at 809 ("a case raising a federal patent-law defense does not, for that reason alone, 'arise under' patent law, 'even if the defense is anticipated in the plaintiff's complaint, and even if both parties admit that the defense is the only question truly at issue in the case' " (*quoting Franchise Tax*, 463 U.S. at 14)).[9]

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9. After *Christianson*, this Court held in *Holmes* that compulsory counterclaims which raise patent issues also do not vest appellate jurisdiction in the Federal Circuit because the Federal Circuit's appellate jurisdiction is determined only by looking to plaintiff's well-pleaded complaint. *Holmes*, 535 U.S. at 830–32.

B. Conflicting Circuit Court Case Law Also Shows That A Patent-Related Claim Gives The Federal Circuit Exclusive Appellate Jurisdiction.

Prior to the decision below, the circuit courts that had considered appellate jurisdiction questions in cases involving patent-related claims found that such cases belonged in the Federal Circuit.[10] Indeed, the Federal Circuit expressly stated that *Walker Process* claims are "subject to exclusive federal court jurisdiction under 28 U.S.C. § 1338(a) because the determination of fraud before the PTO necessarily involves a substantial question of patent law." *Ciprofloxacin*, 544 F.3d at 1329 (reaching this conclusion even though the complaint included other allegations of monopolization that did not rest entirely on patent law). The Seventh Circuit took a similar view in finding that a breach of contract case that turned on whether a product was within the scope of a patent should be heard by the Federal Circuit because the plaintiff there could not obtain the relief it sought without resolution of the patent issue. *U.S. Valves*, 190 F.3d at 813–15. These decisions of the Federal Circuit and Seventh Circuit also conflict with the Second Circuit's decision below.

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10. In at least one case, a regional circuit court decided a plaintiff's *Walker Process* claim without any express mention of whether it was proper for it to do so and with no indication that any party raised an appellate jurisdiction argument. *Kaiser Found. Health Plan Inc. v. Abbott Labs., Inc.*, 552 F.3d 1033, 1043–54 (9th Cir. 2009).

II. THE SECOND CIRCUIT'S DECISION ERODES THE FEDERAL CIRCUIT'S APPELLATE JURISDICTION IN CONTRAVENTION OF CONGRESS'S GOAL OF CREATING UNIFORMITY IN PATENT LAW.

The decision of the Second Circuit, if not reversed, will erode substantially the Federal Circuit's exclusive jurisdiction over patent-related antitrust claims. Under the decision below, if any one of a plaintiff's antitrust "theories" (actually claims) is not based exclusively on the patent laws, the entire case must go to the regional circuit. Pet. App. 15a–16a. This is inconsistent with Congress's intention of creating a national appellate court to harmonize the patent laws and curtail forum shopping in patent cases. *See, e.g.*, S. Rep. No. 97-275 (1981), *as reprinted in* 1982 U.S.C.C.A.N. 11, 15; H. Rep. No. 97-312, at 20 (1981). Congress explained that the "central purpose [of creating the Federal Circuit] is to reduce the widespread lack of uniformity and uncertainty of legal doctrine that exist in the administration of patent law." H. Rep. No. 97-312, at 23.

A. Congress Created The Federal Circuit To Harmonize The National Patent Laws And Eliminate Forum Shopping.

The regional circuits handled patent law issues in a divergent manner before Congress established the Federal Circuit. The House Report accompanying the act creating the Federal Circuit expressly notes that patent law had long "been identified as a problem area, characterized by undue forum-shopping and unsettling inconsistency in adjudications." *See, e.g.*, H. Rep. No.

97-312, at 20–21. Congress also found that "the validity of a patent [was] too dependent upon geography (*i.e.*, the accident of judicial venue) to make effective business planning possible." *Id.* at 21–22. Similarly, courts, including this Court, noted the rifts in patent law that marked that period. *See, e.g., Graham v. John Deere Co.*, 383 U.S. 1, 18 (1966) (observing "a notorious difference between the standards [of patentability] applied by the Patent Office and by the courts"); *Mfg. Res. Corp. v. Graybar Elec. Co., Inc.*, 679 F.2d 1355, 1361 n.12 (11th Cir. 1982) (noting that the circuit law regarding the burden of proof for patent invalidity was "in a morass of conflict"). Congress also established the Federal Circuit's exclusive jurisdiction to address the rampant forum shopping that had plagued patent cases. S. Rep. No. 97-275, 1982 U.S.C.C.A.N. at 15; H. Rep. No. 97-312, at 20–23.

The existence of the Federal Circuit has served to promote the uniformity that Congress envisioned for patent law, including by allowing this Court to focus on key patent law issues (as opposed to dealing with the circuit conflicts that existed previously).[11] *See, e.g.*, H.T. Markey, *The Federal Circuit and Congressional Intent*, 41 Am. U. L. Rev. 577, 577 (1992) (former Federal Circuit Chief Judge Markey reporting that "in its first three years . . . [the Federal Circuit] identified and resolved all of the thirteen conflicts in the previous patent law

11. This Court's caseload and correspondingly limited ability to address patent cases also were also part of the reason that Congress created the Federal Circuit as an "effective means of assuring even-handedness nationwide in the administration of the patent laws." H. Rep. No. 97-312, at 22.

decisions of the regional circuit courts"). The Federal Circuit has resolved, or aided in the resolution of important questions including, for example, determining that claim construction is a matter of law for the court to decide;[12] and determining that Federal Circuit law, and not the law of the regional circuit, applies to questions of attorney-client privilege between a patent attorney and a patentee.[13]

B. Vesting Jurisdiction For Patent-Related Antitrust Appeals In The Federal Circuit Serves Congress's Purpose Of Creating Uniformity In Patent Law.

Congress's intent in forming the Federal Circuit is best served by vesting jurisdiction for antitrust claims that turn on a substantial question of patent law in the Federal Circuit. While not every patent issue is to be heard by the Federal Circuit, having patent-related antitrust claims appealed to the Federal Circuit is well within the balance struck by Congress in setting the Federal Circuit's jurisdiction. Congress recognized as a potential concern that "specious patent claims" would be tied to "substantial antitrust claims in order to create jurisdiction in the . . . Federal Circuit." S. Rep. No. 97-275, 1982 U.S.C.C.A.N. at 29–30; H. Rep. No. 97-312, at 41. But Congress concluded that this concern was unfounded because the Federal Circuit would not have appellate jurisdiction unless one of a plaintiff's initial

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12. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed.Cir.1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996).

13. *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 803–04 (Fed. Cir. 2000).

claims arose under 28 U.S.C. § 1338, and the Federal Circuit would strictly construe its jurisdiction. S. Rep. No. 97-275, 1982 U.S.C.C.A.N. at 29–30; H. Rep. No. 97-312, at 41. Specifically, Congress explained that the appellate courts would adapt the general "arising under" test for federal question jurisdiction to determine whether a plaintiff's claim "arises under" patent law. S. Rep. No. 97-275, 1982 U.S.C.C.A.N. at 29–30; H. Rep. No. 97-312, at 41. And Congress understood that cases raising "patent issues merely couched in antitrust terms" would be appealed to the Federal Circuit. S. Rep. No. 97-275, 1982 U.S.C.C.A.N. at 46.

III. THE SECOND CIRCUIT'S DECISION WILL ALLOW A CLEVER PLAINTIFF TO PLEAD ITS PATENT-RELATED ANTITRUST CLAIMS INTO THE REGIONAL CIRCUIT AND AVOID THE FEDERAL CIRCUIT.

The Second Circuit's decision below threatens the national uniformity of patent law, raises again the hazard of forum shopping in patent cases, and takes important patent law questions away from the Federal Circuit. The decision below will allow private litigants, rather than Congress or the courts, to determine which regional circuit has jurisdiction over the same patent-related antitrust claim by altering the style, but not the substance of their allegations.

This Court has cautioned against adopting rules that permit jurisdiction to be created through creative pleadings. *Fed. Dept. Stores, Inc. v. Moitie*, 452 U.S. 394, 397 n.2 (1981) (*citing* 14 Wright, Miller & Cooper, Federal Practice & Procedure § 3722, at 564–66 (1st ed.

1976) ("[Courts] will not permit plaintiff to use artful pleading to close off [a] defendant's right to a federal forum . . ."). *Christianson* itself states that it is the court's obligation to determine the "real nature" of the claim "regardless of plaintiff's characterization." 486 U.S. at 809 n.3 ("a plaintiff may not defeat § 1338(a) jurisdiction by omitting to plead necessary federal patent-law questions." (*citing Franchise Tax*, 463 U.S. at 22; *Moitie*, 452 U.S. at 397 n.2)). The real substance of a plaintiff's claims—the key that unlocks appellate jurisdiction—cannot change no matter how artfully the claims are styled in the complaint. *Christianson*, 486 U.S. at 809 n.3; *Moitie*, 452 U.S. at 397 n.2.

But the Second Circuit's decision below did not determine the "real nature" of Plaintiffs' claims; it allowed the style of Plaintiffs' complaint—a one-count monopolization complaint—to control the number of substantive claims it found. The Second Circuit's decision thus wrongly promotes form over substance by failing to consider the actual nature of Plaintiffs' well-pleaded claims as required by *Christianson*. As a result, uniformity in crucial areas of the patent law on important questions will be lost. Allowing private litigants to determine which circuit court hears a patent-related antitrust claim is neither what Congress intended in establishing the Federal Circuit's jurisdiction, nor a beneficial development for patent law or owners of intellectual property who rely on relative stability in patent law as they develop and protect their inventions.

CONCLUSION

IPO respectfully requests that the Court grant the petition for a writ of *certiorari*.

Respectfully submitted,

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APPENDIX

APPENDIX

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